

ing this morning about not disclosing any relevant information that might jeopardize an ongoing trial?

Dr. WELCH. I do not think so. The report is more general in nature, and I do not think there is any case within this report, any part of this report which might reflect on the trial. But I would, again, urge caution and certainly give the Army the chance to comment on that question.

Senator LEVIN. We will work with the IG on that so we can arrange for public release of it.

Dr. WELCH. I would hope that it is released, too, because it is very helpful and, again, it underlines some of your findings and some of your recommendations.

Senator LEVIN. Recently there has been an Army environmental impact statement on the biological defense program and it has sections on controversial issues. It makes no reference—even though it is dated May 1988—it makes no reference whatsoever to the problems that have existed at Aberdeen, the investigations conducted by Maryland, by the Army, by the U.S. Attorney.

There is no reference at all to all of that in this environmental impact statement. How do you explain that?

Dr. WELCH. Tom?

Mr. DASHIELL. My perspective—and I would let the Army address this if they would like to in more detail—the problems at the pilot plant I generally consider environmental problems rather than safety problems. The EIS that you are referring to is a generic EIS, a programmatic-wide EIS, and specific details of work in a given facility or given location would have to be followed up with a supplemental environmental statement which would address that specific location.

Senator LEVIN. Is there going to be a supplemental EIS; do you know?

Mr. DASHIELL. I cannot really say at this time. It may well be the case that—

Senator LEVIN. Who would know?

Senator COHEN. Just so we are clear, that draft EIS was not for chemicals but rather for biological.

Mr. DASHIELL. It was for biological; that is correct.

Colonel HUXSOLL, would you want to comment on that?

Colonel HUXSOLL. Yes. I was just going to make the same comment that Senator Cohen has just made, and that is that the recent draft environmental impact statement covered only the biological defense research program, not the chemical.

Senator LEVIN. On the chemical issue, Aberdeen has supplied the Subcommittee with safety inspection reports for 14 CW contractors that the CRDEC monitors. The staff has analyzed these reports for a 2-year period from January 1986 to January 1988, and here are some of the results. The reports, again, came from Aberdeen and they have supplied them to us and have worked with us on this. 13 out of the 14 contractors inspected had safety cabinets with some type of deficiency; half of them, 7 out of 14, failed to have emergency detection kits in the laboratories or the kits were outdated; 6 out of 14 had first-aid kits which were deficient or inaccessible; 6 out of 14 failed to have required waste disposal or waste testing records; 6

out of 14 stored flammable or other hazardous chemicals improperly.

Other problems included inadequate safety plans and training programs, inadequate emergency showers and eyewashes, missing or uninspected fire extinguishers and improper monitoring procedures or records. These are obviously disturbing statistics.

What does the DOD plan to do to improve on the safety of their contractor's operations in the CW area?

Dr. WELCH. I will ask General Hidalgo to respond, but first, these are findings that you have read, findings by Army people who were looking at contractor performance, and I commend the Army for being tough on finding these problems.

It reflects, in my mind, a different perspective on the part of doing civilian work and doing DOD work, and I think it reflects tougher requirements on the part of DOD and contractors to appreciate this. When they do not—and you have just given some statistics that indicate that in some cases they have not—we demand that they fix it before they go on, or if they refuse or are reluctant to do this, we terminate the contract.

But let me ask General Hidalgo to give you some specific answers to your question.

General HIDALGO. Yes, sir. These inspections which we conduct which generated these reports are very, very tough inspections. We go into minute detail. It is not surprising that we would find some of these things. We require that the contractor correct these deficiencies and then we follow up to ensure that they have corrected them.

Senator LEVIN. Do you ever apply sanctions? I know that on occasion you have actually forced a contractor out of the program. But short of that, do we ever impose sanctions for these kind of safety violations such as monetary fines or delaying payments on contracts? Have those types of more limited sanctions ever been applied?

General HIDALGO. They are available. They have not been applied, to the best of my knowledge, in these cases. The ultimate, of course, is to terminate the contract.

Senator LEVIN. Why do we never apply anything other than the ultimate sanction, which is obviously reserved for extreme cases?

General HIDALGO. Because we believe that the contractors are very responsive in correcting these deficiencies. So we tell them to do it, they do it, and they are responsive to our needs.

Senator LEVIN. Let me give you one example of this situation. This is a long-time participant in the CW research program who was inspected in December of last year by the CRDEC and had these safety problems recorded on its inspection report.

This is one participant: "Training is past due and the records are outdated; face velocities in Hood A are excessive due to equipment storage outside the 20 centimeter line; the first 5-day monitoring not conducted or records maintained; emergency showers not tested monthly; labels on CW material waste containers are illegible; both laboratories are extremely dirty; nitric acid stored on lab bench; flammable, non-flammable compressed gas cylinders stored together; excess storage of flammable gas cylinders permitted in laboratory; fire extinguisher missing from the laboratory; unlabeled con-

ainers in the lab; no bleach or decontamination solution stored in lab; fuse box not capped or covered; excess chemicals stored in lab; flammable material was being dumped in lab sink; possibility of organics being released down the lab sink."

There is more. That is probably the most excessive case we found, by the way. I would not want to suggest that that is the typical case, but we found that case. Apparently that contractor did not get the message about safety and something needs to be done, it seems to us, when that kind of a situation is found.

Now, what happens in a case like that? Walk through that with us. That is December of last year.

Can't you develop some kind of a sanction for a case like that? That is not a case of: a lock does not work on a box, that is the only problem, they are willing to fix the lock, and they did not even know it did not work. I mean, this is one safety violation after another by the same contractor.

We are delighted to see that you record problems, by the way. That is a plus, so we are very happy that you do that. But we have got to do a lot better than just record 20 problems with one contractor at one time. We have got to deter that from happening, it seems to me.

Walk through it with us now. Take that situation. Is that just a matter of saying, here contractor, here is our report, fix it up, and that is the end of it?

General HIDALGO. No, sir. We follow up then to see that they have corrected these problems. Perhaps, if you will indulge us, I would like to call on Ms. Wood, who does these kinds of inspections for us and visits these contractor facilities, to describe the inspection and follow-up procedures.

Senator LEVIN. Okay. Ms. Wood?

Ms. WOOD. We turn them over to the contracting agency who has the authority to notify the contractor in writing. The contractor is then required to answer back to the contracting agency that the deficiencies have been corrected and then we revisit the site to ensure that they have been corrected.

Senator LEVIN. Do you happen to know what contractor I am referring to, offhand?

Ms. WOOD. Yes, sir.

Senator LEVIN. Do you know whether or not these problems have all been corrected?

Ms. WOOD. I could not say, sir, that they have been corrected. They are due to be inspected again on the next semiannual inspection visit sometime in September, and that would be verified at that time. Their report has come in saying that they have corrected those deficiencies.

Senator LEVIN. In other words, we have got a representation, in writing, from this contractor that all of these problems have been corrected but we are going to wait until a regular visit to make sure that it has been done?

Ms. WOOD. Yes, sir. We go twice a year. Anything we identify, we verify when we go back on the following inspection.

Senator LEVIN. I wonder if something like that is not egregious enough that we ought to go back and check? I mean, with so many violations at one time, should we wait for the next semiannual visit

to see that they have corrected them all? There are about 20 violations in there. Do we have the capability to go back right away and check it out? Do we have the manpower to do it?

General HIDALGO. Yes, we do.

Senator LEVIN. I would think that where you have that many violations at one time that we ought to do something better than waiting for the next visit. Since you know who they are, would you go back and take a look at them and see whether or not in fact they have corrected everything and let us know whether or not they have?

Ms. WOOD. Yes, we would, sir.

Dr. WELCH. We will be glad to do that, Senator, and it would also seem helpful to all of us if we put all of these contractors into perspective, starting, for example, with the number of first-time violations that were not corrected on the second visit.

Senator LEVIN. That would be fine. All right. Just a few additional questions here. Are you familiar with the testimony from the fire chief yesterday? Did someone report to you on that testimony?

Dr. WELCH. I read some of the reports.

Senator LEVIN. Apparently he did not get word about CW agents in his district which is necessary for his staff to know how to fight any kind of a fire which might happen there. His staff apparently met with the contractor after he did learn about the agents, and at the contractor's suggestion, agreed not to enter the facility in the event of a fire due to toxic fumes, and instead to concentrate on keeping the fire contained. That is the kind of arrangement which should have been reached prior to the materials having been delivered there.

Is there a need to develop a new regulation which would require DOD labs and contractors, as part of their safety plans, to submit statements from their local fire chief that describe some kind of a mutually agreed upon plan to fight fires that might occur at these facilities?

Dr. WELCH. Well, I think the most responsive answer to that question can come from the Army, and I will ask General Hidalgo to respond, and also from a contractor who deals with small amounts of chemical agents for the Army.

General HIDALGO. Senator, we routinely notify the State police and local police whenever we make a shipment of chemical agent material to one of our contractor sites. We also, by contractual clause, require the contractor to abide by all Federal, State and local laws or ordinance that might govern those types of operations.

I would ask, perhaps, Dr. Ted Procife, from Battelle Columbus laboratories, to comment on the community interaction aspects from a contractor's standpoint.

Senator LEVIN. Let me ask you to do that for the record, if you would, because we want to move on. If you could, make that comment for the record relative to my question as to whether or not we shouldn't require a little more formally that a fire chief approve some plan for a fire.

General HIDALGO. We also, I might add, provide to the contractor a Materiel Safety Data sheet which describes the characteristics of the material that they are being provided for their research.

Senator LEVIN. If you could get us the answer for the record to the question about requiring fire chief involvement in this.

We received a letter from DOD in September of last year saying that responsibility for the DOD Biological Defense Program "by implication" is placed in the Office of the Assistant to the Secretary of Defense for Atomic Energy and is vested in his Deputy for Chemical Affairs, which is you, Dr. Welch.

What does it mean when the DOD says that the responsibility for the Biological Defense Program is placed "by implication" with you? Shouldn't it be more explicitly expressed than that?

Dr. WELCH. It is an interesting term, isn't it? Like by coronation or something.

I agree that we could probably at this point better acknowledge the importance of biological defense in the DOD. When my office was established, at my suggestion to the Defense Science Board in 1980, the looming defense issue was chemical. We had a good appreciation of the chemical threat. Now, with the expansion of those countries investing in biological agents, I agree with you there ought to be included in my charter the acknowledgment of the need to do biological defense and to fix the responsibility.

Senator LEVIN. Will you address that issue, then, in your charter? Will you take the steps necessary to see that that is done, or will you suggest to the Secretary that he do it?

Dr. WELCH. I will make that suggestion. I will offer some changes to the charter. And I will keep your staff informed.

Senator LEVIN. Thanks. In July of 1987, the Army Science Board issued a report that was critical of the Army's management policy and structure in the chemical and biological agent research program. Now this has to do with the research itself and not the safety issues connected to it. But here is what the report says:

"There is no single organizational entity other than the Army staff which is responsible for integrating the total biological defense effort. There is a serious lack of clearcut assignment of responsibility together with authority to control the program's direction and output." It also cites inadequate coordination among the involved commands. That suggests some real management problems which could be impacting on safety considerations.

Has any action been taken relative to that finding, since it was made by the Army Science Board?

Dr. WELCH. The Army has a central point of contact on the Army staff reporting to the Chief of Staff, Army, for chemical matters. And again, it evolved in the same way that my office evolved with concerns back in the early 1980s over chemicals. That has also been the office responsible, and I think it has done a good job, for programs dealing with defense, physical defense against biological agents.

The Army Surgeon General has been responsible for the medical defense program against biological agents, so you see there is a split, if you will. I have asked a number of times and have seen good coordination between the two elements, because there is some overlap, for example, when building a biological agent detector. It has both an infantry use, obviously, and a medical use. And we should not be spending money in two programs to develop the same thing. I think there has been good coordination.

I will ask General Hidalgo or Colonel Huxsoll or Tom Dashiell to comment further.

General HIDALGO. Sir, I believe that the context in which the statement from the Army Science Board report was made was in the total structuring of a biological program including defense, force structure, funding, doctrine, training, research and development, all of which, as you pointed out, certainly has some implications in the safety program as well. But I believe they were looking at it in a broader context.

Senator LEVIN. Dr. Welch, do you disagree with the finding of the Army Science Board that there is a serious lack of clearcut assignment of responsibility together with authority to control the program's direction and output? Is that something you simply disagree with?

Dr. WELCH. My own observation is that the Surgeon General of the Army and the Deputy Chief of Staff for Operation responsible for the biological defense program are doing a good job. They are talking to each other. I think the Army Science Board may have been given the impression of the program being controlled by more than one central point, but I think it is important to appreciate the fact that we ought to keep separate the medical defense against biological agents and the physical defense—the masks, the overgarments, and so on—which have in common, by the way, protection against chemical agents.

It doesn't make sense to organize a separate biological defense program at the central point of contact in the Army.

Senator LEVIN. It does not, you say?

Dr. WELCH. Does not.

Senator LEVIN. So you disagree with that finding?

Dr. WELCH. I agree that the proper management is as I find it now, and that is the Surgeon General doing medical defense against biological agents and the Department of the Army staff doing the physical biological and chemical defenses.

Senator LEVIN. Did you want to jump in?

Senator COHEN. I was going to follow up. When you disagree with an assessment that has been made, do you do anything for the record, or you just ignore it?

Dr. WELCH. The Army Science Board deals in chemical and biological issues. The report is brought to me. I discuss it with the Army staff. We agree on what changes we ought to make to implement it, what changes we cannot make for resource reasons but would like to make. When we make recommendations, they often compete with the recommendations of other Army Science Boards presented to the Army Chief of Staff. He has only so many resources to do the job; sometimes we ask for things but can't afford them. But, I am of the belief that management of the Biological Defense Program in the Army is organized well.

Senator COHEN. But my point was, do you do something formally so that we don't have an Army Science Board analysis that says here is what is wrong, you have got a serious deficiency; and it goes either ignored or simply unresponded to by you or someone else, creating the impression either that you don't care or—

Dr. WELCH. The Army Science Board is presented to the Chief of Staff, Army. There are—and the Army people at the table can

elaborate—actions taken on that report. The Chief of Staff wants his staff's position on the report, and when a Defense Science Board presents me with a report on something in my area we do exactly the same thing. It is impossible to be completely responsive to all recommendations of all Science Boards.

Senator COHEN. No. I am just asking if you do something for the record? Do you put a memo in the file saying thank you very much, here is where we disagree with you, I think it is working fine and merging these particular two programs will be counterproductive? Is it something that goes in the formal record for your office?

Dr. WELCH. I would ask the Army to respond to that since it deals with an Army Science Board report.

Colonel MITCHINER. Sir, I can respond to your question about tying up the overall responsibility levels. There is a draft memorandum out now that responds to that tying up of the chemical, nuclear and biological program and delineating specific responsibilities for safety, for operations, for logistics. It specifically outlines who does what in the program. That should be out in the very near future. The draft is being reviewed right now.

Dr. WELCH. I will ask the Army staff to provide to you, Senator Cohen, a direct answer from them, the people who deal with Army Science Board reports.

General HIDALGO. Sir, I would add that one of the recommendations, for example, was that we take a very comprehensive look at the biological threats. That was one of the Board's—and determine what potential impact that has on our doctrine and training and force structure, and that is ongoing, for example.

Senator COHEN. The only point I am trying to make is that I think it is helpful if you have some way of positively responding. You may get a multitude of studies done, investigations and so forth, with various recommendations, some of which will have merit, others which will not have merit. And you ought to be in a position, I think, of saying here is why we think this is a very good point or why we disagree, just so we understand what the Army's position is.

General HIDALGO. And I believe you will find that that is being done. The recommendations are farmed out, the people look at them, they comment on them, and they are reconsolidated, and it is for the record.

Senator COHEN. One other point. I think there was reference made to the fire chief who testified yesterday. As I understand it, Congress has already set standards in terms of when community notification is required for hazardous chemicals. Under the Superfund Reauthorization, Congress set the standards based on quantity as specified by the EPA. And, as I understand it, in this particular case they were of such a low quantity that notice wasn't required—and I think the fire chief indicated that to be his understanding, too. So we have already set standards for community notification.

General HIDALGO. Public Law 91-441, which was passed in 1970, directs that Department of Defense notify the Congress whenever there is a shipment of chemical warfare material. It allows the Department to not—to have to do that if it is for research and devel-

opment purposes and quantities, and we define that as 1 liter or less.

Senator LEVIN. Thank you, Senator Cohen.

Colonel Mitchiner, let me ask you a few questions. You are the director of the Army Safety Office, as I understand it; is that correct?

Colonel MITCHINER. Director of Army Safety; yes, sir.

Senator LEVIN. And we appreciate your coming today. We asked that you be here.

What has been the role of the Army Safety Office in the CBW research program in the past?

Colonel MITCHINER. The charter for the Army Safety Program is to, from a management standpoint, oversee the regulatory requirements, the regulations, the policies, and that sort of thing, and promulgate that guidance out to the field.

Senator LEVIN. So you have not been engaged in inspections?

Colonel MITCHINER. Only from an assistance-type thing or a member of a team. There are only two personnel in the Army Safety Office involved in the chemical-bio program.

Senator LEVIN. Is it fair to say your office has not played a large role so far, particularly in the biological defense program?

Colonel MITCHINER. I think that is probably safe to have said a few months ago. Currently we have a biological regulation in draft that closely parallels the chemical regulation that was referred to earlier, and I expect that to be out soon.

Senator LEVIN. All right. Now the Army has just published a new regulation on its general safety program, AR-385-10, and in reviewing it I notice that it mentions chemical warfare safety concerns in passing and doesn't address biological safety concerns at all.

Now this is what it says about chemical safety: "The Army Deputy Chief of Staff for Operations and Plans will act as focal point for all nuclear and chemical matters." That is the Army Deputy Chief of Staff for Operations and Plans. Does that mean then that you would have no authority over chemical safety?

Colonel MITCHINER. The focal point on the Army staff, sir, the focal point for chemical operations and biological operations is the Deputy Chief of Staff for Operations.

Senator LEVIN. If he is the focal point, then doesn't that leave you out of it?

Colonel MITCHINER. Not at all, sir. Not at all. I am responsible for the safety management and the policies as they pertain to safety. I am the guy that is chartered to write the regulation on the chemical portion for safety and for biological.

Senator LEVIN. And the regulation that I just read makes no reference at all to biological safety. That was on May 23, by the way. That regulation was issued May 23, which is one day before the new BDP directive that we have referred to.

Colonel MITCHINER. That is right. The new biological regulation will address that, and a change to AR-385-10 will direct—now one of the problems we had was the chemical information and the biological information was spread around many different regulations. What we are trying to do and what we have done is write a chemical regulation that brings it all together. And we are writing a bio-

logical regulation that brings it all together for the biological area, and in the other regulations we will put references to those two regulations as to how they will be conducted and where one goes to for the guidance.

Senator LEVIN. By the way, will you submit that pending regulation on the Biological Defense Program to us for the record?

Colonel MITCHINER. When the regulation is published, is that what you are saying, sir?

Senator LEVIN. As soon as you can.

Colonel MITCHINER. Yes, sir.

Senator LEVIN. Would you submit it to us as soon as you are legally able to do it?

Colonel MITCHINER. Yes, sir.

Senator LEVIN. One of the questions that we would like you to comment on is the suggestion that your office should be the coordinator of safety programs in the chemical and biological portions of the CBW program. What is your reaction to that?

Colonel MITCHINER. Well, I guess my initial reaction would be, sir, from a management standpoint I feel like we are. That we promulgate the regulations currently in coordination with the other agencies. As I mentioned, certainly we have two personnel in the office, safety, chemical and biological specialists, to deal with those things.

Senator LEVIN. I mean beyond promulgation of regulations, though, and in terms of implementation as well. Should you have a role in coordinating that program?

Colonel MITCHINER. The Director of Army Safety is responsible. That is the office for Army safety responsibilities there.

Senator LEVIN. For coordinating, now?

Dr. WELCH. For all Army safety, it is my understanding, to include chemical and biological. Of course, we have chemical safety and security offices, at Edgewood, for example, that deal directly with contractors, with the laboratories, and are responsible at that level. But on the Army staff, it is the Colonel and the Director of Army Safety that has overall Army responsibility.

There is, as we said this morning, the establishment of a biological defense safety and security office. It, in turn, would be for staff functions responsible on up to the Director of Army Safety.

Senator LEVIN. This is what the IG's report indicates on this subject, that the U.S. Army Safety Office, "focal point for other Army safety matters, is not recognized by the field as having any chemical safety responsibilities or expertise." Now this is just on the chemical side that this IG report is commenting. But that seems to be totally at odds with what you just said.

Dr. WELCH. I think the expertise, if you ask these people what they meant by that, is with the chemists and other scientists at the Army's Surety and Safety Offices at the Chemical R&D Center. I would hope, as the Colonel has said, there is at least one or two of his office here at the Pentagon responsible and knowledgeable of what the subject matter experts do at places like Edgewood.

He can't be responsible, and his office can't be responsible, to maintain expertise in aviation and armored vehicles and chemical and so on. His is a policy function. It is an oversight function, and

he has got to, certainly, rely—I think you would agree with me, rely on subject matter experts at places like Edgewood.

Senator LEVIN. That is not quite what the IG is saying, though. Let me read you two statements of the IG and just ask you whether you agree or disagree with them in this report.

The evaluation revealed that the Army level chemical safety mission execution suffers from a lack of published policy guidance, inadequate staffing, no systematic program of oversight, and a less than clear statement of safety responsibilities.

Dr. WELCH. I would agree with some qualifications.

Senator LEVIN. And the second is: "As a result, the USASC, focal point for other Army safety matters, is not recognized by the field as having any chemical safety responsibilities or expertise."

Would you agree or disagree with that point?

Dr. WELCH. I would disagree again with qualification. I think the second point is one of education. I think what they have put their finger on is the matter of education. People must recognize that we are dealing more and more with threat biological agents. The program has expanded. There is a need for corresponding safety and security regulations as we have discussed this morning and as your majority staff has recommended. This is all part of this education progress: the promulgation of regulations, the training, the new procedures. I am sure that once those things are done, for example, a year from now when you ask your staff what has happened or what is new in this area that you will find a much improved situation.

Senator LEVIN. I made reference before to an environmental impact statement on the Biological Defense Program, and in that statement the following is written: "The controls in effect throughout every aspect of the BDRP are adequate and implementation of more stringent monitoring, or development of criteria to provide further protection for the workforce or the external environment, are not considered to be necessary."

Now that was on May 12 when the report was released. Yet within two weeks after that the Army Medical Research and Development Command, MRDC, which is in charge of the BDP, issued a new directive implementing new controls. Among other things this directive, which, of course, we welcome as we have said before, made the CDC and the NIH biological safety rules mandatory for all DOD labs and contractors, established a safety inspection system, and ordered procedures to be developed to ensure that all BDP labs comply with relevant safety rules.

And then again, two weeks after that, on June 15, you issued a second directive requiring the Navy and the Air Force also to follow the CDC-NIH biological safety rules.

How could it be that on May 12 everything was adequate and then we had, within literally two weeks, the agreement that we did need some additional safety controls?

Dr. WELCH. I will let the Army and, perhaps, Tom Dashiell respond. But allow me to make one observation. And that is, as you noted yesterday and today, we are in a dynamic situation, an ever-increasing appreciation of safety. This shows up in our procedures, our regulations, and so on. So I don't want to take the position that we have had a static outlook on safety. It is dynamic, and you are

going to see from time to time some jumping ahead in one area ahead of another. For example, one regulation reflecting this new awareness of safety in one area might outdistance another action that is in the works. And I might say that draft EISs do take enormous amounts of time and staffing and can become dated.

But let me ask the Army to respond. Tom?

Mr. DASHIELL. I would only add to what Tom has said. That is a draft environmental impact statement. It has been made available for public comment, for anybody's comment. We just recently had the last scoping meeting. We have had a variety and a large number of comments, and there is no question that the draft will be revised to accommodate those. I am sure that it probably was somewhat dated when it was first issued.

Senator LEVIN. That it was what?

Mr. DASHIELL. It was probably somewhat dated when it was issued. It takes about a year to publish, put that all together.

I would like Colonel Huxsoll to comment, if he would.

Colonel HUXSOLL. I guess that the people who put together the draft environmental impact statement did not consider that the system was broke, but that the Medical Research and Development Command felt that a little preventive maintenance might be important. Thank you.

Senator LEVIN. Dr. Welch, what do you think of the idea of designating the CRDEC as the lead chemical safety office?

Dr. WELCH. It seems to me there has to be fixed responsibility. Once the Secretary of Defense assigns executive agency responsibility to the Secretary of the Army, he is responsible for all aspects of that program to include safety. He is, of course, assisted by the Chief of Staff and a very deliberate chain of command which fixes responsibility for certain areas right down the line.

Senator LEVIN. We have got the ICD and the Defense Logistics Agency doing safety inspections, too. Would it not be desirable to have a lead agency, lead safety office?

Dr. WELCH. It seems to me the Army can do a good job with safety, and I think what you are seeing is, as you said in your statement, the evolution of better regulations, better procedures, better training. I would like to see the system work before we do anything like establishing something outside of the executive agency.

And I would ask that we give these new regulations, these new procedures, this new awareness, new education programs, the IG recommendations, the staff recommendations, the GAO recommendations about a year or so to work, and come back and revisit this area and see how well we have done. We can count on the Office of the Secretary of Defense to call for some in-process reviews during that period, and I think when we come back you will be very pleased with the results.

Senator LEVIN. In the biological defense area, we heard from certain witnesses yesterday that there are some shortcomings in the program, one witness asserting that DOD protocols concerning the conduct of biological agent research are outdated.

How often are the protocols for the BDP program updated?

Dr. WELCH. Colonel Huxsoll?

Colonel HUXSOLL. If you are referring to the regulations and so forth that govern safety, they are updated on a continuum. If you would take a look at the regulations, some of which I happen to have with me—many of them have very recent dates, but we are talking about—

Senator LEVIN. Are you talking about the protocols that govern these programs? The conduct of the biological agent research, is that what you are referring to?

Colonel HUXSOLL. Mr. Chairman, I guess I would have to ask you what you mean by protocol?

Senator LEVIN. Okay. Do we have a protocol, for instance, for a written evacuation plan for a facility in case of an accident or an incident?

Colonel HUXSOLL. I would be happy to address that from the standpoint of USAMRIID.

Senator LEVIN. No. I mean DOD. Does DOD have a protocol?

Colonel HUXSOLL. I am not aware that DOD has a protocol for evacuation of a facility because I believe that that would be peculiar to that facility.

Senator LEVIN. So there is no recent set of rules that the DOD has relative—

Colonel HUXSOLL. To my knowledge, sir, that is correct.

Senator LEVIN. And nor should they, in your view?

Colonel HUXSOLL. That is right, sir.

Senator LEVIN. Each facility should have its own evacuation rules?

Colonel HUXSOLL. That is right, sir.

Senator LEVIN. And does each facility have a written evacuation plan?

Colonel HUXSOLL. I can address that from the standpoint of USAMRIID.

Senator LEVIN. Do we know overall whether each facility has a written evacuation plan? Dr. Welch, would you know?

Dr. WELCH. I would ask, perhaps, General Hidalgo or others familiar with contracting procedures to respond to that.

Senator LEVIN. General Hidalgo?

General HIDALGO. Certainly for chemical research contractors, they are required to have an evacuation plan.

Senator LEVIN. And do they? Do we know? Do they have written evacuation plans, each of the contractors?

General HIDALGO. They do.

Senator LEVIN. Okay.

General HIDALGO. That is one of the things we check when we inspect them.

Senator LEVIN. Just one question that I want to see if we can—this will be the last question. Yesterday a former researcher at USAMRIID, Dr. Neil Levitt, testified concerning his fears about a possible contamination of a rhesus lung cell that was used in his work. And when we asked the DOD representatives in the room if they might have an answer for us today, I don't know if they got back to you or not. Dr. Levitt said that despite his misgivings a Junin virus vaccine was being developed and produced using these cells and is or was being tested in human volunteers at USAMRIID.

Do you know whether or not that vaccine was tested for possible contaminating organisms? We wanted to try to find that out by today. Do you know the answer?

Dr. WELCH. Colonel Huxsoll?

Colonel HUXSOLL. Yes, I can address that. Those cells and the vaccine itself were indeed tested, and there is no evidence of any adventitious agents in that vaccine.

Senator LEVIN. Would you supply the Subcommittee with the tests on that vaccine?

Colonel HUXSOLL. Yes, sir. No problem whatsoever.

Senator LEVIN. Let me add this one question. I think you were represented here yesterday and your representatives I believe heard some of the testimony that we received from the Yale witness. The witness was a member of the Yale Biosafety Advisory Committee, but in response to questions seemed to have little familiarity with Yale's safety personnel, procedures, and practices. He was uncertain of the Yale safety director's name, wasn't sure when his lab had been inspected during the last year and a half, wasn't sure whether copies of inspection reports were in his files—there were none in the University's files over that year and a half period—and wasn't aware that the biological safety officer doesn't use a checklist anymore in conducting those inspections.

Were your representatives here yesterday surprised by that seeming unfamiliarity by that witness, and did that reinforce your determination to have the DOD do some oversight of your contractors?

I think Colonel Huxsoll may have been here yesterday, although I am not sure. So either you could answer it or whoever may have been here yesterday could answer. That struck me as being evidence that we really do need to have some oversight from the outside of our contractors. And I am wondering whether you or your representative here yesterday were struck the same way by that testimony.

Dr. WELCH. That particular testimony suggested to us that we must proceed with these new regulations we talked about, and which you welcomed. We must pay more attention to the biological defense side, reflecting as much as we can what we have learned to be fruitful on the chemical side. It is part of what you said in your opening statement this morning, Mr. Chairman. And it is an important part, but I think it is important to realize it is just one part. You said it is now time to review past mistakes, fix the programs that are not working and establish new procedures that take us where we want to go. That is our sentiment, and this example you have cited is going to be fixed.

Senator LEVIN. Dr. Welch, you and your colleagues, we thank you for your testimony. There is a roll call on, so we are going to recess now for 10 minutes before we take up our next panel. But you are all excused, and thank you for coming.

[Brief recess.]

Senator LEVIN. Thank you all for your patience, if I may describe it that way. You may not have had any choice, but we will thank you for your patience.

Our next panel consists of Dr. John W. McVicar, who is Director of the Office of Biosafety, Centers for Disease Control, accompanied

by Dr. Michael P. Kiley, Microbiologist, Office of Biosafety; and also on the panel is Dr. Joseph E. Rall, who is the Deputy Director for Intramural Research at the National Institutes of Health.

Thank you all very much and you may proceed. Your testimony will be made a part of the record.

Dr. McVicar?

TESTIMONY OF JOHN W. McVICAR, M.D., DIRECTOR, OFFICE OF BIOSAFETY, CENTERS FOR DISEASE CONTROL, ACCOMPANIED BY MICHAEL P. KILEY, PH.D., MICROBIOLOGIST; AND JOSEPH E. RALL, M.D., DEPUTY DIRECTOR FOR INTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH

Dr. McVICAR. Thank you, Mr. Chairman. I do not have a prepared statement at this time. I would just like to point out that I have brought with me Dr. Michael Kiley who is a recent addition to our staff and comes to us from the Centers for Infectious Disease, having had a long time of experience in microbiological laboratories, and in particular, high containment labs. We will try and answer your questions and speak to your concerns.

Senator LEVIN. All right. Did any of you want to begin with an opening statement?

Dr. RALL. I have prepared some rather informal remarks that you might be interested in. I am Edward Rall.

Thank you, Mr. Chairman, for your invitation to appear before this Subcommittee. I have spent over 40 years working in laboratories and I would like to contrast the situation say 20 or 30 years ago with the situation today with respect to several different aspects of safety; chemical, biological and radiological safety. Since radiologic safety is largely regulated and inspected by the Nuclear Regulatory Commission, I shall say no more about it.

With respect to chemical safety, our methods of analysis a few decades ago were relatively crude. We could not measure small quantities of materials, so we had to make large quantities of material. Not only that, most of the compounds we made and the experiments we did were with organic chemical-type reagents. We used strong acids and bases, powerful oxidizing and reducing agents. This meant at the NIH and, indeed, in most laboratories, there were occasional fires and explosions in spite of our safety measures.

With respect to biological materials, we did not know much about the life cycle of some of the organisms, nor the modes of transmission, and unfortunately occasionally scientists working with pathogenic organisms acquired the disease.

The situation has changed dramatically. In the first place, we now use modern biological materials and techniques, such as enzymes and the general methods of recombinant DNA. This requires very small amounts of material and in general the working conditions are very tame. We do not use strong acids or bases and we do not use strong oxidizing agents. So we have seen a remarkable reduction in the number of fires and explosions.

In addition, we now have extraordinarily sensitive instrumentation for measuring very small amounts of material, so we use much lesser quantities of material.

Senator LEVIN. May I interrupt you just for one moment, Doctor, on an unrelated matter.

Dr. RALL. Please.

Senator LEVIN. After this panel is completed, we are going to ask Colonel Huxsoll to come back and to give us a comment which we would welcome relative to some of yesterday's testimony. There may be members of the audience here or the media that might be interested in that fact. It is not relating to your testimony directly, but we wanted to let people know that we will be inviting Colonel Huxsoll back to give us some testimony which he did not present earlier today.

Thank you, Doctor.

Dr. RALL. With respect to biologicals, we are in much better position than we were some decades back because we know so much more about how they are transmitted, their infectivity, their life cycles, and a variety of other things.

Now, if I could be more specific, one of the questions the staff posed was what safety precautions can be taken to minimize risk. There are two categories of risk. One risk is posed by potent chemical compounds that interfere with specific biological functions. One group is the so-called cholinesterase inhibitors, which were ingredients in a poison gas. These are very lethal. Actually, some analogs of these are used as common pesticides and you can get them in the local gardening store.

One of these compounds is diisopropyl fluorophosphate. Now, it turns out it is a specific compound and it is very useful, occasionally, in quite general biological laboratories. So we have to be very careful about these very potent compounds. We use them but we keep antidotes at hand, and we handle them with great care.

Then there is risk from the variety of toxins used. I should say, I know what is being done in chemical and biological warfare only from what I read in the popular press or what I can imagine would be reasonable for any such laboratory to do. There are several varieties of potent chemical compounds. There are the very potent proteins, the biological materials such as tetanus toxin, ricin, batrachotoxin.

All of these compounds require different precautionary measures. The people working with some of them can be immunized against tetanus toxin, diphtheria toxin, pertussis toxin. Others one has to be very careful with. Some are very sensitive to alkali, some to acid, so you have appropriate neutralizing agents at hand. Some of them like methyl mercury are somewhat volatile and you have to be extraordinarily careful in working with those under a hood.

A committee of the National Academy of Sciences, of which I was a member some years back, considered these possibilities of chemical hazards in the laboratory and published a book, "Prudent Practices for Handling Hazardous Chemicals in Laboratories," and I have it here. We use this book extensively in our training courses in chemical safety.

Now, let's consider the risk from infectious agents, which you have asked about. This includes, essentially, all the pathogens known to man. Prominent among them at this time are hepatitis B, HIV virus—the cause of AIDS—and a whole variety of other ones. Hepatitis B and HIV have been acquired in the laboratory on

a very few occasions throughout the world as a result of needle sticks and cuts with broken glass. We have had extensive training courses and we have a manual devoted to this, trying to educate anyone who works with infectious agents as to the dangers and the precautions that must be taken.

The book which was referred to before, put out jointly by the Centers for Disease Control and the National Institutes of Health, entitled "Biosafety in Microbiological and Biomedical Laboratories," was published in 1984 and we use this extensively as a guideline. There are four levels of risk. All agents known at the time are listed and evaluated according to the risks they pose and the safety levels that should be used. The book has been revised and the revised version is now in press.

Perhaps I could conclude by noting that the safety branch at the National Institutes of Health held a symposium just a few months ago on future problems of safety in the laboratory and there were some hundreds of representatives from universities and Federal Government laboratories and a substantial representation from industry. There was universal agreement, and particularly by the representatives of industry, that in the coming years we would have to give more emphasis and more resources to laboratory safety.

Thank you for this opportunity. I will be pleased to answer any questions you might pose.

Senator LEVIN. Thank you very much, Dr. Rall.

First, let me ask both you and Dr. McVicar about the CDC-NIH rules that we have referred to. As I understand it, those rules set up safety procedures and physical equipment requirements for labs working with infectious agents. Those rules do not, nor do they purport to, set inspection schedules for labs, require certifications of compliance with safety rules, require or establish an accident reporting system, set forth storage rules, require emergency plans, require notice to fire departments and things like that.

So would you agree that the Department of Defense comprehensive safety regulation, for instance, for the biological defense program, is going to have to go further than the CDC-NIH rules; would you agree with that, both of you?

Dr. McVICAR. Yes, I would say so. The plan, being comprehensive, would perhaps go beyond these guidelines which are specifically for infectious agents.

Dr. RALL. I agree with Dr. McVicar. I should point out, these are not rules, these are guidelines, and the NIH in particular has no regulatory or inspection responsibilities except for our own laboratories and there we, of course, have a rather elaborate system of training courses and inspections.

Senator LEVIN. Those guidelines, though, have been made mandatory in some instances, have they not, in some areas of the Government?

Dr. McVICAR. I believe DOD has often included the CDC/NIH guidelines in their contract requirements, yes, sir. As Dr. Rall points out, these are guidelines. They do, however, assume a regulatory tone when they are made as a requirement by some contractual document giving some legal oversight.

I think in terms of the comprehensiveness of a safety plan, as was pointed out earlier, and I would like to emphasize that point, too. We make this point with our researchers, and that is to be a useful plan there has to be some aspects that come from the local area, from the laboratory itself. This requires, then, that these plans be specific for that area, in addition to the general recommendations that may come from a general set of guidelines such as these.

Senator LEVIN. I understand that the National Academy of Sciences is going to propose some new guidelines; is that correct? New safety guidelines in this area?

Dr. McVICAR. I cannot speak specifically to that because I have not seen them. However, I have spoken to one of the co-editors or authors of that set of guidelines and it was indicated to me that in general these are going to be, perhaps, an enhancement, or basically a restatement of these general rules.

Senator LEVIN. Did that person tell you or do you otherwise know of any changes which are going to be made that you could identify for us?

Dr. McVICAR. I could not identify them. We did not go into details.

Senator LEVIN. Dr. Rall, do you know of any changes?

Dr. RALL. I can add no more.

Senator LEVIN. In your opinions, are regular, systematized safety inspections necessary for labs engaged in experimenting with the types of agents that are used in chemical and biological warfare in defense research?

Dr. McVICAR. Certainly. I would like to add that we think one of the most important aspects of a safety program is an adequate training program. We can have all the guidelines or rules we want but if the people do not know what they are doing, they are going to run into trouble. So we feel this is one of the essential parts of maintaining a safe laboratory environment.

Senator LEVIN. We have talked about education. We have talked about safety inspections. What about accident drills? Are either of you familiar with those kinds of drills? Are they used frequently in these kinds of labs?

Dr. RALL. We really do not have drills other than fire drills. It is difficult to know what kind of drill to undertake in the sense that if you cut your finger when you are dealing with blood or virus or a broth with a toxic agent in it, there is not much point in having a drill if you know exactly what you are supposed to do.

Dr. McVICAR. I would second that. This idea of training and being prepared is certainly a large part of any safety program.

Senator LEVIN. In the chemical side, apparently these drills are used for accidents.

Dr. RALL. We do not have a procedure for such a drill.

Senator LEVIN. Given the hour, we are going to ask some additional questions of you for the record and we would appreciate, if you could, getting us some written answers.

Again, thanks for your patience this morning. Thank you.

Dr. McVICAR. Thank you, Mr. Chairman.

Senator LEVIN. Colonel Huxsoll, thank you for waiting. We wanted to give you the opportunity to address some of the testimo-

ny which was submitted yesterday about past safety problems at USAMRIID. You are the Commander there, so fire away.

Colonel HUXSOLL. Thank you very much, Mr. Chairman. I appreciate this opportunity.

There has been a lot of discussion in the course of the last few days relative to safety and the importance placed upon it. I can say that at USAMRIID, safety comes first, and any suggestions that we compromise safety in order to use our budget for other purposes is not the situation at USAMRIID.

We fear that maybe some irreparable damage has been done by the testimony of one of our former employees to the credibility and effectiveness of the safety program at USAMRIID, a program which has been emulated by many other laboratories and which is considered to be, along with CDC, the epitome of high-hazard containment.

The testimony given was ridden with half-truths, exaggerations and totally false statements. The actions taken in response to the incidents cited are not only explainable but were justifiable and in no way compromised the health of the employees or the environment or connotated a lack of attention to employee concerns.

One of those was the so-called missing vaccine virus. I would like to go back and just very briefly review that. Dr. Levitt attempted to produce chikungunya vaccine on three different occasions.

Senator LEVIN. What kind of vaccine?

Colonel HUXSOLL. The chikungunya virus vaccine.

Senator LEVIN. Okay.

Colonel HUXSOLL. And all failed. In the third attempt failure was due to contamination of the vaccine. There was a mix-up between the bottles infected with the vaccine virus and the controls. In fact, a bottle of vaccine was mixed with the controls so that there was an extra bottle of control.

I would like to read from the laboratory records of that time. It says: "Note: Remember that one of the 250 ml bottles of vaccine turned up missing and ended up with the controls, had too much control fluid, so who did what to mix them up?"

I think that clearly points out that they recognized that the vaccine—there was a mix-up in the vaccine and the vaccine was actually at that point not worth keeping.

Dr. Levitt was directed to destroy the material, and this is done by autoclaving. Further, Dr. Levitt was directed to switch to a different cell line, the MRC 5 cell line, not because there was any problem with the Fetal Rhesus Lung cell line but the MRC 5 cell line produced a greater quantity of the vaccine virus and thus it was much more efficient.

Subsequently, the vaccine virus which was supposed to have been autoclaved was then reported, "missing." An informal investigation lead management to conclude that the material had probably been destroyed through autoclaving as was directed.

Senator LEVIN. When was that investigation?

Colonel HUXSOLL. That was immediately after the incident.

Senator LEVIN. So that would be in what? 1981?

Colonel HUXSOLL. In that timeframe, sir. Management recognized further that the vaccine was indeed attenuated and also presented no threat.

Now, in 1983 I became Commander of USAMRIID. This was several years after the vaccine was alleged to have been missing. In 1986, the missing vaccine became an issue with reports to the press, the IG, a Congressional inquiry, and I felt that although the incident had occurred several years earlier—in other words, before my time—I needed all the information I could get.

I appointed a board of officers, pursuant to AR 15-6, to investigate the allegations of the missing vaccine, and I would like to summarize directly from that report. The board of officers concluded that if any vaccine preparation left the suite it was autoclaved.

However, the report—which is right here, you can see how thick it is—which I received contained testimony of one individual who alleges that Dr. Levitt had told him that he, Dr. Levitt, had consulted a tarot card reader concerning the missing vaccine and that the tarot card reader described the culprit as a person with the same physical characteristics of a technician who worked in the lab at that time.

It is the opinion of the board of officers that an adequate investigation was conducted by members of the supervisory chain and that the laboratory commander's decision to consider the case closed was fully justified. They did recognize that the management may not at the time have communicated that well with the laboratory workers.

After careful review of Dr. Levitt's laboratory notebooks, the board concluded that it was impossible to determine how much material was dispersed or misplaced. However, what was ascertained conflicted with the memorandum for record dated December 30, 1981. In addition, three of the signatories of the MFR agree that portions of the document are in error.

The final comment I would like to make is that the board of officers concluded that the physical security of USAMRIID's containment areas is considered adequate to reasonably prevent the theft of infectious agents by other than personnel authorized to enter the areas.

That is all I have to say on that topic.

Senator LEVIN. Why don't I just interrupt you there and ask you a couple of questions about this.

Colonel HUXSOLL. Sure, I would be happy to.

Senator LEVIN. The Army IG concluded in May of 1986 that, "The inquiry * * * substantiated Dr. Levitt's allegation that no investigation was conducted into the disappearance of the virus, however, management did consider the matter and determined an investigation was inappropriate since the virus was not biologically hazardous."

Would you agree with that statement of the IG?

Colonel HUXSOLL. That centers around what you call an investigation. There was no formal investigation; that is correct.

Senator LEVIN. Well, he did not say no formal investigation. He says: "The inquiry, therefore, substantiated Dr. Levitt's allegation that no investigation was conducted into the disappearance of the virus, however, management did consider the matter and determined an investigation was inappropriate since the virus was not biologically hazardous."

I am just wondering whether you agree with that formulation, that conclusion?

Colonel HUXSOLL. The issue on not hazardous, not being hazardous, or the investigation?

Senator LEVIN. No. That there was "no investigation."

Colonel HUXSOLL. Okay. There was an informal investigation, and let me explain what I mean by that. A number of years ago, before I had all these other sorts of duties, I worked at a laboratory bench myself in a virology laboratory. And when we had something that came up contaminated or for whatever reason was unfit for further study or use, it was destroyed. It is just simply too easy to go back and redo that. And so it is quite understandable to suggest that if it were of no value, autoclave it, get rid of it, and it was assumed that he followed instructions and had in fact done that.

And I can understand why—

Senator LEVIN. So you would not agree that there was "no investigation"? What you would say is that there was an informal investigation?

Colonel HUXSOLL. Yes, sir. That is correct.

Senator LEVIN. So that you disagree with the Inspector General on that characterization?

Colonel HUXSOLL. On that fine point, I do, sir.

Senator LEVIN. Is it true that all persons in that laboratory that handled the missing virus said that they did not autoclave it? Is that true?

Colonel HUXSOLL. It is believed by one of the senior technicians that she in fact had autoclaved that material.

Senator LEVIN. There was somebody there who said they believed they did autoclave it?

Colonel HUXSOLL. They believed they autoclaved the material. And by the way, some of that material was subsequently found.

Senator LEVIN. After she said she autoclaved it?

Colonel HUXSOLL. Yes, sir. Now, I have got to put this together, as we are talking about something that happened in 1980 and now it is up to 1986. But even sometime afterwards, going back through freezers and inventorying freezers, some of that material was indeed found.

Senator LEVIN. Who was it that said that she autoclaved it?

Colonel HUXSOLL. She believes that she autoclaved it.

Senator LEVIN. And then it was later found?

Colonel HUXSOLL. And some of it was later found. She believes that she autoclaved some of it. In other words—you have got to remember that you have whole material which are cells uninfected, and then you have the vaccine, which are tissue cultures which are infected. And so there are multiple bottles. And I can understand how part of those could have been saved for whatever reason and the others autoclaved.

Senator LEVIN. Wasn't there a contemporaneous document that was signed by all persons in the lab that handled that particular missing material who said that they did not autoclave it? Wasn't there a contemporaneous document signed by everybody?

Colonel HUXSOLL. Is this the memorandum that has four signatures?

Senator LEVIN. Yes.

Colonel HUXSOLL. Subsequent to that there was an addendum—

Senator LEVIN. The "that" being December 30?

Colonel HUXSOLL [continuing]. That you do not have, sir, or may not have.

Senator LEVIN. The four-signature document is dated December 30?

Colonel HUXSOLL. Right. And there is a follow-on to that.

Senator LEVIN. Okay.

Colonel HUXSOLL. And the follow-on is signed by just one of the persons.

Senator LEVIN. One of the four?

Colonel HUXSOLL. Yes, sir.

Senator LEVIN. And that would be Helen Ramsburg?

Colonel HUXSOLL. That is right, sir.

Senator LEVIN. Is that part of your report there?

Colonel HUXSOLL. Yes it is, sir.

Senator LEVIN. Would you supply that to us for the record?

Colonel HUXSOLL. Yes, sir. I would like to caution you that I need to seek some legal counsel on that because it does contain some material that may impinge upon the privacy of a number of individuals, so we need to work that out.

Senator LEVIN. Fine. That would be fine.

I believe that the Inspector General told the staff of the Subcommittee that there was no evidence to support the autoclaving claim, so if in fact our staff heard him right, you would disagree with that?

Colonel HUXSOLL. That is right. It is hard to tell what happened after 6 years, but the memo that she wrote was written in that interim.

Senator LEVIN. And that is evidence, you are saying, to support the autoclaving claim?

Colonel HUXSOLL. One would not necessarily record everything that they autoclaved and one cannot remember all those different types of material that are autoclaved.

Senator LEVIN. I understand that. But you would characterize that document as evidence to support the autoclaving claim?

Colonel HUXSOLL. Yes, sir.

Senator LEVIN. Do you know whether Major Bettencourt, who was the IG here, saw that document?

Colonel HUXSOLL. He certainly would have had access to it, I think, but I was never given an opportunity to discuss with him any of his findings.

Senator LEVIN. He never discussed his findings with you before he made them?

Colonel HUXSOLL. No, sir.

Senator LEVIN. How about after he made them?

Colonel HUXSOLL. No, sir.

Senator LEVIN. Did you get a copy of his report?

Colonel HUXSOLL. No, sir.

Senator LEVIN. Okay. Do you want to proceed?

Colonel HUXSOLL. There is one other incident that I would like to bring up. It had to do with the fire. In testimony yesterday we were told about a fire that occurred in a laboratory and it was implied

that containment had been compromised and that water was running out of the doorway and doors were propped open and that kind of thing. I think it is important to set the record straight on that.

First of all, I think we have a very good track record with fires. In the 18 years that we have enjoyed occupying the current building, we have had only two very, very minor incidents and both of these occurred with faulty equipment where there was a short and basically that piece of equipment had caught fire and actually they self-extinguished.

What I would like to do is read from the actual fire report made by the Fort Detrick fire department. On the front it says that they responded with an administrative vehicle, that no pumper actually responded to the fire. And in addition, no hose streams or fire extinguishers were used because the fire occurred sometime prior to 0430 hours, which was the time of the freezer alarm indicating elevated freezer temperature and was actually discovered at approximately 0652.

Our entire building is monitored by a computer, so all of the incubators, all of the freezers, all of the high containment suites are monitored and when the fire occurred in the freezer, of course the freezer was damaged so that it was no longer operable. And as the temperature began to rise, it reached the critical point when it sounded the alarm.

So that is what actually occurred. And I would like to read from the report further. It had a mixture of freon and pentane and it was highly flammable. Fortunately, we do not have those kinds of freezers anymore, and I believe that probably the acquisition of that freezer was based, again, upon low bid.

But nevertheless, the mixture of gas coupled with an electrical fault at a glass-type seal at the 208 volt connection causes fires when the seal fails due to heat and the escaping gas is ignited by electrical arcing or by high heat at the connection. An identical fire of this type occurred in the National Cancer Institute building on this installation in March 1981.

Now, when the alarm was sounded, one of the technicians was called at 0430 in the morning and he saw no need for immediate action because the freezer alarms at temperatures within the range of 15 degrees centigrade, above the sub-freezing temperature of minus 60 to 70. Consequently, the contents remain stable for several hours if the freezer remains closed.

When he arrived at Building 1425, he entered the laboratory, and he realized a fire had occurred and apparently had self-extinguished. He did this at 0652 in the morning. So there were no hose streams or fire extinguishers used in the fire and the fire actually self-extinguished. The report also further states that, "USAMRIID has initiated a work order to the facilities engineer, Fort Detrick, on the feasibility of installing heat or smoke detection in the entire building," and we have done that.

I wanted to correct that point.

Senator LEVIN. What was the specific statement, then, or statements that you are refuting?

Colonel HUXSOLL. The point that was made in testimony yesterday was that there was water running out of the suite, suggesting

that the water had been used to extinguish the fire and in one way or another containment may have been compromised.

The point is that no water was ever used. And in addition to that, the suite was really no biological hazard of any kind because they were producing a vaccine, and at that point you are interested in protecting the vaccine because you are actually developing something you are going to put into man. And so at that point, if it has to be kept at that level of containment, a high level of containment, you certainly would not have something that was ready to go into man.

Senator LEVIN. Ready to go where?

Colonel HUXSOLL. To go into man, into somebody's arm.

Senator LEVIN. So that the first statement that you disagree with is the statement that water ran out of the hot suite and into the hallway? You are saying there was no water?

Colonel HUXSOLL. There was no water used.

Senator LEVIN. And the second one is what?

Colonel HUXSOLL. The point is that that suite was no longer under high containment because they were in the process of making a vaccine and at that point—

Senator LEVIN. What particularly—is it in his written testimony? Do you know?

Colonel HUXSOLL. I do not know if it is in his written testimony or not.

Senator LEVIN. Your colleagues back there are shaking their heads yes, so apparently it is in his written testimony. Could you identify the particular line?

Colonel HUXSOLL. Yes.

Senator LEVIN. What page are you on?

Colonel HUXSOLL. It is on page 5. It says here that, "Detrick personnel wandered in and out during the confusion and from that time on and without any decontamination procedures, the lab was considered cold and special safety precautions no longer applied."

Well, the lab was cold when the vaccine was being made.

Senator LEVIN. It was cold before the fire?

Colonel HUXSOLL. Yes, sir.

Senator LEVIN. So it is not "from that time on"?

Colonel HUXSOLL. That is right.

Senator LEVIN. I got you. Okay. There is another witness that we have talked to, who prefers to remain anonymous, who says that water was sprayed outside of the suite.

Colonel HUXSOLL. I cannot comment on that—

Senator LEVIN. That water was "sprayed into the room to put out the fire and was permitted to flow out again outside of the suite." So you just disagree that water was sprayed into the room?

Colonel HUXSOLL. Yes, because when the fire department arrived, the fire was out. It self-extinguished.

Senator LEVIN. Well, that does not mean water was not sprayed.

Colonel HUXSOLL. I cannot comment on that. Again, we are talking about something—

Senator LEVIN. Are you saying that water was not sprayed into the room? Or are you saying that the fire was out?

Colonel HUXSOLL. Well, we have evidence from the fire report that the fire was out and no hose lines were laid and that type of

thing. That is the only thing that I have. I have no evidence that water was sprayed into the room.

In addition to that—

Senator LEVIN. But you are not flat out saying water was not sprayed into the room?

Colonel HUXSOLL. That is right, sir, I am not.

Senator LEVIN. Okay. We thank you for coming forward, and if there is any additional material you would like to submit to us, we would appreciate it.

Let me ask you one question. There is some confusion on this document I referred to as having four signatures and the document in your file.

Going back to the first instance of the missing material, is the four-signature document that you referred to dated December 30, 1981? Can you just double check that document?

Colonel HUXSOLL. Yes, sir, that is the one. It has the four signatures on the second page.

Senator LEVIN. Yes. And we were trying to find here quickly where that document made reference to a contemporary autoclaving. We are not sure now that it does. But in any event, you seem to have the same impression, so maybe we are under a common mis-impression. But we got that from somewhere. We are not sure it is this document.

Colonel HUXSOLL. It is somewhat of a strange document in that four people signed it but all four did not agree with everything in the document.

That is why if you look along the right-hand side you will see—it is difficult to make out—initials.

Senator LEVIN. I see. But is there a reference in that document to contemporaneous autoclaving?

Colonel HUXSOLL. It is in the addendum and I am hunting for it right now.

Senator LEVIN. Is that the addendum what you said you would submit to us for the record?

Colonel HUXSOLL. Yes, sir, I can.

Senator LEVIN. And that was a later addendum?

Colonel HUXSOLL. Yes. I am trying to find that date on that.

Senator LEVIN. Okay.

Colonel HUXSOLL. I have it right here. It was dated January 1986.

Senator LEVIN. The date of the addendum is what?

Colonel HUXSOLL. 1986. I will just read that.

Senator LEVIN. Yes. Could you read just that one portion so we do not have to worry about the privacy issue. This was just signed by the one person, right?

Colonel HUXSOLL. Okay. It says: "If by chance the vaccine material in question was autoclaved out to permit safe disposal of useless material and not stolen, no record of this was made in the notebook as it should have been."

Senator LEVIN. If by chance it was autoclaved?

Colonel HUXSOLL. Right.

Senator LEVIN. I thought that was the document which said that she remembered autoclaving it?

Colonel HUXSOLL. It only suggests that maybe that is the way it left the laboratory.

Senator LEVIN. I got you. Okay. And just to correct the record, I am no longer clear that the document I referred to, which is the December 30, 1981, document signed by four people says that it was not autoclaved. We cannot, at least this quickly, find that reference, so I think I mis-spoke at that moment. Where we got that impression from is some other document or somewhere else, or we may be in error on that.

But in any event, I think the record is clear. We would appreciate it, if you get clearance from your lawyer and can work it out, that you get us a copy of that addendum dated—what was the date in 1986?

Colonel HUXSOLL. Yes, it was in 1986; October 1986.

Senator LEVIN. October 1986. You also made reference to a fire report and we could not get a copy. They did not seem to have one left in the fire department, so could you submit to us your copy of that fire report?

Colonel HUXSOLL. I would be very happy to sir.¹

Senator LEVIN. Colonel, we thank you and, again, we appreciate your coming forward. We are sorry we did not get to you before but we hope we made up for it.

Colonel HUXSOLL. I appreciate the opportunity. Thank you very much. I feel much better.

Senator LEVIN. Good, Colonel. So do we.

[Whereupon, at 12:20 p.m., the Subcommittee adjourned subject to the call of the Chair.]

¹ See p. 210.

APPENDIX



DEPARTMENT OF THE ENVIRONMENT

201 WEST PRESTON STREET • BALTIMORE, MARYLAND 21201

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William Donald Schaefer
Governor

Martin W. Welsh, Jr.
Secretary

STATEMENT

OF

HAROLD LLOYD DYE, JR.

MARYLAND DEPARTMENT OF THE ENVIRONMENT

HAZARDOUS AND SOLID WASTE MANAGEMENT ADMINISTRATION

HAZARDOUS WASTE ENFORCEMENT DIVISION

BEFORE THE

UNITED STATES SENATE

SUBCOMMITTEE ON OVERSIGHT OF

GOVERNMENT MANAGEMENT

DIRKSEN SENATE OFFICE BUILDING

ROOM 342

WASHINGTON, D.C.

WEDNESDAY, JULY 27, 1988

Good morning Chairman Levin, Senator Cohen and Members of the Subcommittee. My name is Harold Lloyd Dye, Jr. I appreciate this opportunity to speak to you today as a representative of the Maryland Department of the Environment.

In my testimony, I will describe the conditions I witnessed and the observations I made while conducting inspections at the United States Army's Aberdeen Proving Ground. I will confine most of today's comments to conditions at the Chemical Research Development and Engineering Command (CRDEC), one of the Department of the Army's tenants at Aberdeen Proving Ground. In particular, I will outline the events at CRDEC's Pilot Plant that led to the comprehensive environmental and safety audit conducted at Aberdeen Proving Ground by the Maryland Department of the Environment and the United States Army.

I am presently the chief of the Hazardous Waste Enforcement Division, Enforcement Program, Hazardous and Solid Waste Management Administration, State of Maryland Department of the Environment. I have worked with Maryland's environmental programs since 1978. Prior to my current position, I was an inspector and then a Section Head in the Hazardous Waste Enforcement Division. As an inspector in the Division from 1982 through 1986, I received comprehensive hazardous waste training which includes facets of industrial chemistry, manufacturing processes, toxicology, legal requirements, how to conduct field inspections, and investigative techniques.

Maryland's hazardous waste laws and regulations are substantially equivalent to the Federal Resource Conservation and Recovery Act (RCRA) requirements. The Maryland Department of the Environment's Hazardous and Solid Waste Management Administration (HSWMA) is authorized by the Federal Environmental Protection Agency (EPA) to operate the Maryland hazardous waste program in lieu of the Federal requirements under RCRA.

Under its program, Maryland issues permits for the treatment, storage or disposal of hazardous waste, and conducts inspections and investigations at all industrial sites in the regulated community.

The Hazardous Waste Enforcement Division in particular maintains that responsibility for enforcement of the laws and regulations pertaining to the handling and management of hazardous waste by the regulated community. The Division inspectors perform physical, on site inspections at sites that generate, treat, store or dispose of hazardous wastes. The inspector's function is to evaluate and determine compliance with the handling of those hazardous wastes.

Aberdeen Proving Ground is located in Harford County, Maryland, and is bordered on it's east side by the Chesapeake Bay. Aberdeen Proving Ground is physically separated by the Bush River into two major areas, the Aberdeen area and the Edgewood area. The area is, by land mass, over 30,000 acres in size with over 2,000 buildings or structures located on the Proving Grounds. Over forty tenants conduct research in military warfare at Aberdeen Proving Ground. By far, one of the largest tenants

located at the Edgewood area is the Chemical Research Development and Engineering Command. Through their activities, the tenants at Aberdeen Proving Ground generate a variety of hazardous and nonhazardous waste streams.

The State of Maryland regulates the Aberdeen Proving Ground under a State issued Controlled Hazardous Substances permit. Since November 18, 1981, Aberdeen Proving Ground has been operating a controlled hazardous substance storage facility at the Edgewood area under the Federal interim status and State run hazardous waste programs. On September 25, 1985, Maryland re-issued the permit which allows Aberdeen Proving Ground to continue to store its generated hazardous wastes in accordance with the terms and restrictions of the permit. The permit also allows treatment by incineration of certain waste streams at the Edgewood area.

During the period from 1981 to 1985, I was the State of Maryland's inspector assigned to inspect the management of hazardous wastes at Aberdeen Proving Ground. My inspections concentrated on the storage of hazardous wastes at the Edgewood area storage sites and the DECON/DETOX incinerator, also at the Edgewood area. The State's contact for environmental affairs at Aberdeen Proving Ground was the Environmental Management Office (EMO) which was the on base organization that had the responsibility for assuring that hazardous wastes and materials were properly managed. All hazardous wastes generated from the tenant sites were to be turned in to the Environmental Management Office for processing, either to the permitted storage buildings or for off-site removal and disposal.

During the late afternoon of September 18, 1985, the Environmental Management Office of Aberdeen Proving Ground notified the State of a sulfuric acid spill behind building number E5625, CRDEC's Pilot Plant, at the Edgewood area of Aberdeen Proving Ground. I was the inspector who responded from this Administration. When I arrived at the Pilot Plant that same afternoon, I learned that approximately 200 gallons of concentrated sulfuric acid had leaked from a faulty flange in an above-ground tank, cracked through a concrete dike and leaked to the Canal Creek, a tributary of the Gunpowder River which is a tributary of the Chesapeake Bay. My visit was the first time that a representative of the State had been to the Pilot Plant area and I was unaware of the existence of this building and its operations prior to the spill response. Information reported to me by the Environmental Management Office on the function of the building was that it was used for testing the efficiency of "raw" nerve agents. At no time during the episode of the acid spill did I physically tour or inspect the Pilot Plant.

While responding to the acid spill, I noticed that the compound that included the Pilot Plant was under armed security guard and fenced in with dual razor wire fences and signs posting "Use of Deadly Force Authorized". The acid spill caused the water of the Canal Creek to exhibit a measure of pH in the range of 1 to 2 which is highly acidic and which caused a fish kill of species identified as yellow perch, blue gills and eels. The effects of the acid spill decreased linearly as the creek approached the Gunpowder River. To counteract the effects of the

acid spill, the Environmental Management Office in agreement with the State, treated the creek with limestone and sodium bicarbonate. Follow-up inspections on this spill were focused on ameliorating the affects of the acid spill, and not on the operations or material handling of the Pilot Plant. However, due to the fact that the tank farm dike adjacent to the Pilot Plant failed to contain the spilled acid, questions were raised on the efficacy of spill containment and prevention not only at the Pilot Plant, but at other areas of Aberdeen Proving Ground where hazardous materials were stored which, if released, could adversely affect the public health and the environment.

Following the acid spill and frequent visits by the State to mitigate the effects of the acid spill, Aberdeen Proving Ground's Environmental Management Office personnel inspected the Pilot Plant and found a myriad of problems with sumps, sewer lines, chemicals and potential sources of contamination of surface water and groundwater at the Pilot Plant. These problems were documented in an internal memorandum for record from an Environmental Management Office staff engineer on October 22, 1985. (See Attachment A) Yet, the acid spill documentation provided to the State on October 28, 1985, made no mention of the October 22, 1985, memorandum on the Pilot Plant and the findings by its author. It was not until January, 1986, when a newspaper reporter from the Baltimore Sun disclosed a copy of the October 22, 1985 memo to the State (from the reporter's confidential source at the Pilot Plant) that the State had knowledge of the extent of the problems at the Pilot Plant. The

memo and allegations of illegal disposal practices at the Pilot Plant were immediately referred for criminal investigation to the Maryland Office of the Attorney General.

In conjunction with inspectors from the United States Environmental Protection Agency, the State made its first tour of the Pilot Plant on February 19, 1986. (See Attachment B) I was one of two state inspectors present during this tour. I was overwhelmed with the haphazard storage of hundreds of drums, bottles and containers of chemicals in virtually every room and hall visited as well as the apparent deteriorated condition of the building. We immediately raised many questions about the handling of chemicals, the integrity of "toxic sumps", sewer lines, floor drains and the operation of an in house incinerator.

In one location, a liquid was observed leaching from the fourth floor and dripping onto the third floor into a drain. A test of the liquid showed it to register a pH of less than 3. No satisfactory explanation could be given by CRDEC personnel as to why this liquid exhibited this acidic characteristic. A room designated as lab 1-I was initially locked. We wished to gain entry as we wanted to sample the "toxic" sumps in the plant. One of the sumps had been identified as being in this lab. Upon entry, extremely strong organic odors were detected. I put on an organic cartridge respirator, however, the odors broke through the cartridges immediately. In our haste to leave the room due to concerns for physical safety, we quickly sampled the "toxic" sump and left without obtaining comprehensive observations of the

lab's contents. We realized that the initial tour of the Pilot Plant raised far more questions than answers due to the overwhelming number of observations.

I performed subsequent inspections at the Pilot Plant on a number of days, each inspection revealing more problems. (See Attachments C, D, and F) During my March 3, 1986 inspection, Aberdeen Proving Ground personnel informed me that the sewer pipes from the Pilot Plant were confirmed to have leaks. In fact, one test showed that a fence post for one of the Pilot Plant security fences went through the top of a sewer pipe. The types and amounts of waste materials that had leaked from the Plant through the sewers to the surrounding environment is unknown.

My inspections of perimeter buildings at the Pilot Plant compound also revealed numerous containers of chemicals. Containers of unknowns were in various stages of deterioration. Peroxidizable compounds, which are unstable, were also discovered. The amount of materials inside and outside of the Pilot Plant that were incompatible and stored adjacent to each other can only be speculated.

On the evening of April 2, 1986, the State received information indicating that a massive cleanup of the Pilot Plant area was underway in preparation for a visit from Congresswoman Helen Delich Bentley. Allegations were made that untrained personnel were being used to handle and remove chemicals and equipment. The state dispatched another investigator and myself to observe the handling of the chemicals and materials at the

site. Upon arrival at the Edgewood Area Entrance Gate, we were denied entry onto the site. (See Attachment E) It was not until the following day that we were granted access and finally observed the alleged disposition of materials from the Pilot Plant.

Subsequent to this event and the State's inspections at the Pilot Plant, the State asked for and received copies of the Army's Inspector General Reports for the Pilot Plant. This report confirmed that the Pilot Plant workers during previous years of operation were subjected to unsafe and unhealthy working conditions, including lack of ventilation, unsafe lighting and electrical connections, deteriorated stairs and roof and excessive storage of hazardous chemicals inside and outside of the building. Due to environmental and safety problems at the Pilot Plant, the State recognized the need to conduct a comprehensive environmental and hazardous material handling practices audit throughout the entire Aberdeen Proving Ground installation. Although the Army also began its own internal audit, the State's audit was conducted independently.

Commencing in June, 1986, and culminating more than one year later, an eight person inspection team from the State began its building by building survey of each tenant on the base. A total of 1,100 buildings were thoroughly inspected and aerial flights of the more remote areas on the base were conducted. Throughout this effort, the U.S. Army did provide assistance to the inspection team by granting access to restricted areas and providing knowledgeable escorts at all times, with the condition

that one week's notice on which buildings the State would be inspecting was provided in advance.

The State's environmental audit of the Aberdeen Proving Ground documented violations of State and Federal hazardous waste management regulations in 89 different areas of the base. All CRDEC buildings were part of this environmental audit. Even with advanced notice, conditions were found where excess chemicals were stored in a manner not consistent with sound environmental and safety practices. Containers of waste materials were found in open fields and without proper containment, drums were cracked open and leaking, and at least one deteriorated open drum of fuming nitric acid was found behind a building during State inspections.

Though several apparent unpermitted wastewater discharges were discovered, the most common violations pertained to State and Federal hazardous waste storage and labeling regulations. In summary, these regulations require a generator of hazardous waste to:

1. identify the waste;
2. label the container with the date of accumulation;
3. store the waste in a containment structure and in such a manner that incompatible wastes can not comeingle;
4. perform weekly inspections, and
5. remove the waste to a permitted facility for storage treatment or disposal within 90 days after accumulation.

The documentation of the numbers and types of violations at a Federal facility staffed by experts responsible for the handling and management of hazardous materials indicates a major deficiency in the training of tenant personnel to manage this problem and also in the facility's own inspection system to assure compliance by its tenants.

The State found that tenant groups were unclear of their individual responsibilities which resulted in inaction and the violations noted. The prevailing attitude among tenant organizations was that the submission of waste "turn-in" documents to the Environmental Management Office relieved the tenant from any further responsibility to safely manage hazardous waste. Each group must clearly understand their duties and responsibilities if the system is to be effective in the future. Regardless of any changes in the existing management system, it is the tenants themselves that must properly manage their own waste on a daily basis.

The State believes that Aberdeen Proving Ground must effectuate a uniform operation procedure for hazardous waste management, ensure that the procedure is implemented, and adequately fund and staff a compliance oversight group. The Aberdeen Proving Ground is, in the eyes of the State, one hazardous waste generator and, as such, the responsibility for compliance rests with the safety office, each tenant, and each individual waste handler.

In addition, the State found a significant need for additional safe storage facilities both at the sites of accumulation and on the base as a whole.

It is significant to note that the Army's own internal audit, the 15-6 Report, and the State's Generator Survey were similar in both their findings and their recommendations to correct the deficiencies found. The following items summarize the basic items that the State believes Aberdeen Providing Ground must achieve to maintain a system that effectively manages hazardous waste in a manner consistent with State and Federal regulations.

1. The development of a comprehensive waste management strategy that focuses on the expeditious disposal of accumulated waste thereby reducing the need for on-site storage.
2. The institution of a training program to educate personnel to manage hazardous waste in compliance with State and Federal regulations.
3. The designation of a group to ensure compliance by all tenants with sufficient funding and staffing to complete this assignment.
4. The development of sufficient containment areas to permit the safe storage of hazardous waste at all generator locations.

5. The upgrade of existing buildings or construction of new buildings to serve as central storage units and the implementation of an adequate operational plan.
6. The completion of remedial actions at the Edgewood facility.
7. The development of Standard Operating Procedures (SOP) for hazardous waste accumulation at all satellite locations.

Hopefully, the actions outlined in the Department of the Army's 15-6 Report and the recommendations outlined herein will be fully executed, and the Department of the Army will reexamine this exercise, determine what procedures work best, how to effectively implement the program and transfer this knowledge to other facilities with similar problems.

ATTACHMENT A

STATE-PS-X

22 OCT 1985

MEMORANDUM FOR RECORD

SUBJECT: CRDC Pilot Plant Environmental Issues

1. The recent sulfuric acid spill from the acid tank at the subject pilot plant (Bldg #E5625) which occurred 18 Sep 85 has surfaced some serious questions regarding operations and environmental controls at the facility. There exist many additional chemical feed, neutralization, reactor and storage tanks which are questionable for future safe usage as well as a complete lack of adequate containment of all such tanks. Additionally, existing storm and sanitary sewers are receiving wastewater from processes within the plant that have virtually destroyed APC sewer lines, and have carried uncontrolled discharges into Canal Creek. At present, no one at CRDC can guarantee that an additional environmental incident could not occur again immediately or in the near future from this facility.

2. On-site inspection of the existing storm and sanitary sewers by the undersigned on 23 and 24 Sep 85 as well as discussion with plant operators and maintenance personnel revealed a virtual "Pandora's Box" of potential sources of contamination of surface water and ground water that suggests the entire plant, especially all operations within Building #E5625, should cease until a complete and thorough environmental study is performed of the facility. The study should as a minimum answer the following questions:

- a. What are the contents of all the tanks, sumps, pits within the entire compound?
- b. Exactly where do all discharges leaving the buildings and diked areas in the compound go? through what channels and pipes (i.e. sanitary or storm) are such wastes discharged?
- c. Are the neutralization and decontamination operations being performed correctly?
- d. Who and how often are pH monitoring equipment and probes checked, cleaned and calibrated? Are calibration logs kept? What are the ages of the equipment and probes?
- e. Are caustic tanks and pipe lines sound or do they need replacement? Are there any existing tank or line leaks? If so, do leaks enter the sanitary or storm sewer lines and at what points?
- f. Are toxic sump pits and storm pits cracked which could allow ground-water contamination? When were such pits last tested to ensure no leaks to the groundwater?

WHILE YOU WERE AWAY

FOR

John

DATE

1/23

TIME

JMI

22 OCT 1995

C-PE-R

SUBJECT: CRDC Pilot Plant Environmental Issues

g. Are level controls cleaned, checked and calibrated regularly? Are logs kept?

h. How often are acid and caustic pumps checked for corrosion? Are logs kept on repair and replacement dates?

i. What operations are on-going within the buildings, especially #E5625, which could allow spillage on floors? What procedures are followed in such cases to contain inplant spills? If any spillage goes to floor drains, does spillage enter the sanitary or storm drain system or toxic holding tanks?

j. How mechanically safe and reliable are all caustic lines and tanks on top of Bldg #E5625 as well as lines within the building itself?

3. The above suggested study is considered absolutely imperative before any operations are started up again at the pilot plant. Without question, no operations involving caustic or acid for neutralization or any operations producing wastewater flows or in-plant floor drainage should be allowed under the present status quo. Our field investigation revealed sink drains within Bldg #5616 that drain directly into the storm system and ultimately into Canal Creek. However, on 24 Sep 85, we traced a discharge of paint into the same storm sewer back to this very same sink. This is an unbelievable illegal practice that was caused by a contractor who poured paint down the drain. The DEM contract inspector has since warned the contractor not to do this again.

4. Based on the information and observations of only a few hours of investigation and discussions, it is highly probable that all of the plant piping, tanks, sumps, drains, etc. are suspect of having been corroded internally and even externally to such an extent that the entire system needs complete repair by replacement. None of the exterior concrete retaining walls and berms are adequate to contain any spillage from acid or caustic solutions. Not all exterior tanks are even bermed at all. All exterior tanks need to be dismantled along with all piping, pumps, probes, and other apparatus. Then, if CRDC needs to continue this mission, all berms need to be completely rebuilt and re-lined with impregnable liners commensurate with the raw chemical solutions to be stored therein. Of course, all new tanks, pumps, and apparatus as well as controls need replacement unless CRDC can produce adequate justification that any such equipment is still sound in construction and reliable for future use. Additionally, none of the existing storm sewers and sanitary sewers can be used between Bldgs. 5625 and 5616 without a thorough inspection and repair or replacement to ensure no ground-water seepage will occur. All such lines from this area to Canal Creek need replacement or abandonment with new lines constructed. It is highly probable that the recent concentrated sulfuric acid spill as well as past undocumented spills and discharges have destroyed portions of the storm and sanitary lines and that

SUBJECT: CRUC Pilot Plant Environmental Issues

5. Recommend that CRDC be required to shut-down immediately all pilot plant operations except where no wastewater would be generated, until a thorough environmental engineering study can be conducted of the conditions of all systems as delineated above to ensure no more environmental spills or regular uncontrolled discharges will occur again. This is not a situation to take lightly in light of the recent acid spill that caused a fish kill, the state regulatory agency's concerns over this plant and the obvious potential for additional catastrophic occurrences. The Commander APG's technical staff needs to have a complete, documented justification to allow this pilot plant to operate again. This should include the recommended study as well as a thorough on-site briefing and plant inspection to be attended by the Commander APGISA, the DEN, the Chief Utilities, the Chief EMO and his staff as well as necessary APGISA Safety Office personnel.

CP:

AFGISA, Safety Office.
AFGISA, Security Office.
Dir. DEM
Chief, Utilities
Chief. ER-D
Chief. EXO

ATTACHMENT B

STATE OF MARYLAND — DEPARTMENT OF HEALTH AND MENTAL HYGIENE

MEMORANDUM
 Copies {
 Ron Nelson
 Don Andrews
 Ed Hammerburg
 Paul Stancil

Thru: John Koonitz/Art Crple AC

TO Aberdeen Proving Ground From Butch Dye BD Date 2/27/86
FileSubject Pilot Plant Investigation

On Wednesday, 2/19/86, Paul Stancil and myself, Harold Dye, Jr. met with EPA representatives and Aberdeen Proving Ground Chemical Research and Development Center (CRDC) representatives to conduct a tour of the CRDC's Pilot Plant at the Edgewood area due to recent publicity surrounding the Pilot Plant. (Copies of recent Sun paper article on the Pilot Plant are in the Aberdeen Proving Ground Enforcement File). Note: A partial list of attendees is attached.

Initially, the group met with General Klugh, the Commanding Officer with CRDC, who presented a slide show about the CRDC's mission in regard to chemical agents, detection, retaliatory capacity, etc. General Klugh advised that all of the slides shown to us would be made available upon request. I requested copies of the slides from Ms. Rosemary Austin of the APG Environmental Management office by phone the morning of Friday, 2/21/86. Surmised from presentation by General Klugh: There are no plans for the production of binary agents at the APG facility; the majority of facilities at Edgewood were built in response to a wartime environment and strict environmental concerns may not have been taken into consideration during construction of the buildings; the Pilot Plant is reported to be approximately 50 years old, and has a working force of 23 personnel; renovation on building was not performed due to projected costs; there have been no pure agents in building subsequent to 1984; there are no chemical surety materials in building; there are no chemical agent operation in building now and none are planned.

Pilot Plant work involves two intermediate binary agents, DC and DF. Combination of these 2 intermediate produces a chemical nerve agent. (It is not clear to me the exact processes performed at the Pilot Plant, however, I believe the work involves testing the combinations of the 2 intermediates to provide research on combination efficiency, purity, etc., which will be used to generate data on production of the binary materials elsewhere). Per General Klugh, binary munitions stockpiling is authorized for 1985/1986 (defense budget). The plan is to replace "unitary" agent munitions with binary agents, with the policy to store agent intermediates in 2 different states.

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Following General Klugh's slide presentation, the meeting was opened to questions. Of immediate concern to myself was the system of drains in the Pilot Plant. Mr. Hugh Riley, of CRDC, responded to my questions as follows:

There are two(2) systems of drains inside the Pilot Plant. One system is called the "toxic" drain and discharges to a "toxic sump" or sumps. The other system is the "septic" drain and handles, supposedly, sewage from sinks, toilets, etc.. The chemicals processed into the "toxic drain" system are charged with caustic (NaOH) to raise the pH to 12 or greater and placed into "toxic sump" until the material is neutralized with acid prior to discharge into sanitary sewer drains which go to the on-base wastewater treatment plant. Per Mr. Riley, the system was a continuous feed neutralization system until the September 1985 acid leak which necessitated the treatment system to become a "batch" system. There was no confirmation on the integrity of the drain and sewer systems. A list of chemicals that are discharged into the sumps/sewer systems was not available at the meeting. There is also a system of storm drains around the building and steam lines constantly discharging steam condensate into both storm and sanitary drains, per Mr. Riley. I questioned Mr. Riley on the constant flow from the storm outfall involved with the acid spill to which he replied that the constant flow was due to steam condensate water and groundwater during periods of dryness.

Pilot Plant Tour

At the Pilot Plant, the group met with Mr. Carl Gepp, Manager, Pilot Plant, after going through the security gate. We initially toured the outside area and site of the acid spill, with Mr. Gepp pointing out the tank that suffered the leak, the concrete dike and storm drain. Steam condensate lines were observed draining condensate into the storm sewer. Test with pH paper showed no observable colorimetric change from the steam condensate.

Moving into the Pilot Plant, we entered by the south hall entrance. Floor drains were in the hall and one drain, directly inside the south hall door, had some steam condensate going into it. Mr. Gepp identified this drain, as a storm drain to receive condensate (a system of steam pipes was just inside the opening and condensate was draining to the drain). Floor drains inside the hall drain to the sanitary sewer lines. Mr. Gepp explained that all drains inside the halls drain to the sanitary lines. All rooms within the inner walls drain to the toxic sump. There were some drums of materials, "Irritant" labels, in the hall (first floor). Most of these drums were empty per Mr. Gepp. I questioned whether there was a spill plan for the materials in the hall to which Mr. Gepp said no and that any spilled material would go to drains, however, he said that any material in the

Page 3

halls were solids. This was not verified. Moving into the inner rooms, the first room was not in use, however, we noted two 5-gallon plastic jugs which were waste liquids, a mixture of Pinacolone, Formaldehyde, t-amylchloride, and 2-methyl 2-butone by the label. Per Mr. Gepp, this material was to be picked up by the Environmental Management office for CHS storage. Moving through other areas we came to a room with an incinerator in a glass enclosed room. The incinerator was reported to have a capability for solid and liquid feed. Natural gas fired furnace, burning/incinerating methyl chloride gas waste generated in a second floor process. Gases go through a water quench system through a caustic scrubber to a vertical demister and through a charcoal filter. A negative pressure is supposedly always kept in any glass enclosed room. Next to the incinerator room was a room with a "reverse osmosis water purification" system to remove hazardous materials from water with drains in the room going to the sanitary sewer. I'm not sure what goes on here. The next room we looked at was the "toxic sump" room. In this room was a 4,000 gallon sump. Per Mr. Gepp, material in the sump is pumped from here to a 4,400 gallon horizontal tank (outside), then to a neutralizing reactor where concentrated sulfuric acid is added for neutralization, then to a second holding tank (where it is tested for neutralized pH) and then to a sanitary sewer. Chemicals are supposedly broken down into ordinary salts by this process. We noticed several containers in this "toxic sump" room labeled with "QL", "DF", and one 5-gallon metal container with Polyisobutylmethacrylate. These containers were not all empty. The pH in the sump water registered between 6-7 with pH paper. I advised Mr. Gepp that we would like to get some samples of the liquid in the sump. (We were told that there were three (3) sumps inside the Pilot Plant and we asked to sample all three).

From here, the group went to the third floor and Mr. Bud Thomas, Senior Engineer for the Pilot Plant, guided the group. In the north end of the third floor hall, there appeared to be an area where liquid was leaching from the fourth floor and dripping onto the floor into a drain. pH paper test showed the liquid on the floor to register ≤ 3 . No satisfactory explanation could be given for this observation. (When we went to the fourth floor, floor brick was deteriorating and probably related to drip on third floor. Possible spill of corrosive material may have caused this. There were drums of "Thionyl Chloride" stored on the third and fourth floors. On the third floor is lab known as the Limited Production Facility (toxic capsule), Lab 3E. Process not clear to us, however, generated methyl chloride here is pumped to the incinerator. No caustic added to methyl chloride; only spent scrubber water discharged to toxic sump. DF bottoms were in distillation material. Sophisticated lab equipment in this room with reactors, vessels, etc., in another glass enclosed room. On the fourth floor, more apparatus in glass enclosed room related to third floor process. Thionyl Chloride drums in rooms and halls. Thionyl Chloride is used in the binary process. On

Page 4

roof are two caustic tanks, one in-service and one empty. From here, Paul Stancil and I separated from the rest of the group and went to get sampling equipment, escorted by Mr. Thomas.

We sampled the toxic sump room sump first, at 1518 hours. Three VOA samples were taken, one given to CRDC for a split. The second sump was in the east side of building. Opening to the sump, approximately 3' by 3' was crumbling. We lowered an approximately 12' ladder down into the sump. (round, bricklined; water appeared about 8 feet deep). Samples taken at 1528 hours, again 3 VOA's. The third sump was located in what was called the Lab 11 room. This room was locked and, upon entry, strong organic odors were detected. I wore a half-mask respirator and odors broke through immediately. Opening to the sump was approximately 1' by 1'. Liquid layer was less than one foot from the top of the sump. Unknown depth or capacity of the sump. A heavy oil/scum layer was on top of an aqua blue liquid. Again, three VOA's were taken at 1531 hours. In our haste to get samples and get out of the room due to concern about personal safety, we did not get good observations of the room's contents.

Following the tour, the group met in Mr. Gepp's office, EPA asking to look at some records. We asked for a flow diagram or something to indicate standard operating procedures for waste streams, which will be sent to us by the APG Environmental Management Office. Following this, the tour ended.

Obviously, this tour of the Pilot Plant has raised more questions than answers due to an overwhelming number of observations. With the waste streams, treatment, integrity of pipes, etc. a closer scrutiny is needed. It may be that a treatment permit (CHS) is needed for what has been described. Questions on what chemicals are being treated, how they are treated and how the neutralization of chemicals occurs still remain.

Included as attachments are diagrams of the Pilot Plant, approximate locations of sumps, and a description of waste stream flow from what I understood and surmised from tour of the Pilot Plant. Also, we never toured the second floor of building.

HD:dl

Attachments (2)

ATTENDEES AND REPRESENTATIVES

Harold Dye, Jr
Paul Stancil
Jerry Crutchly

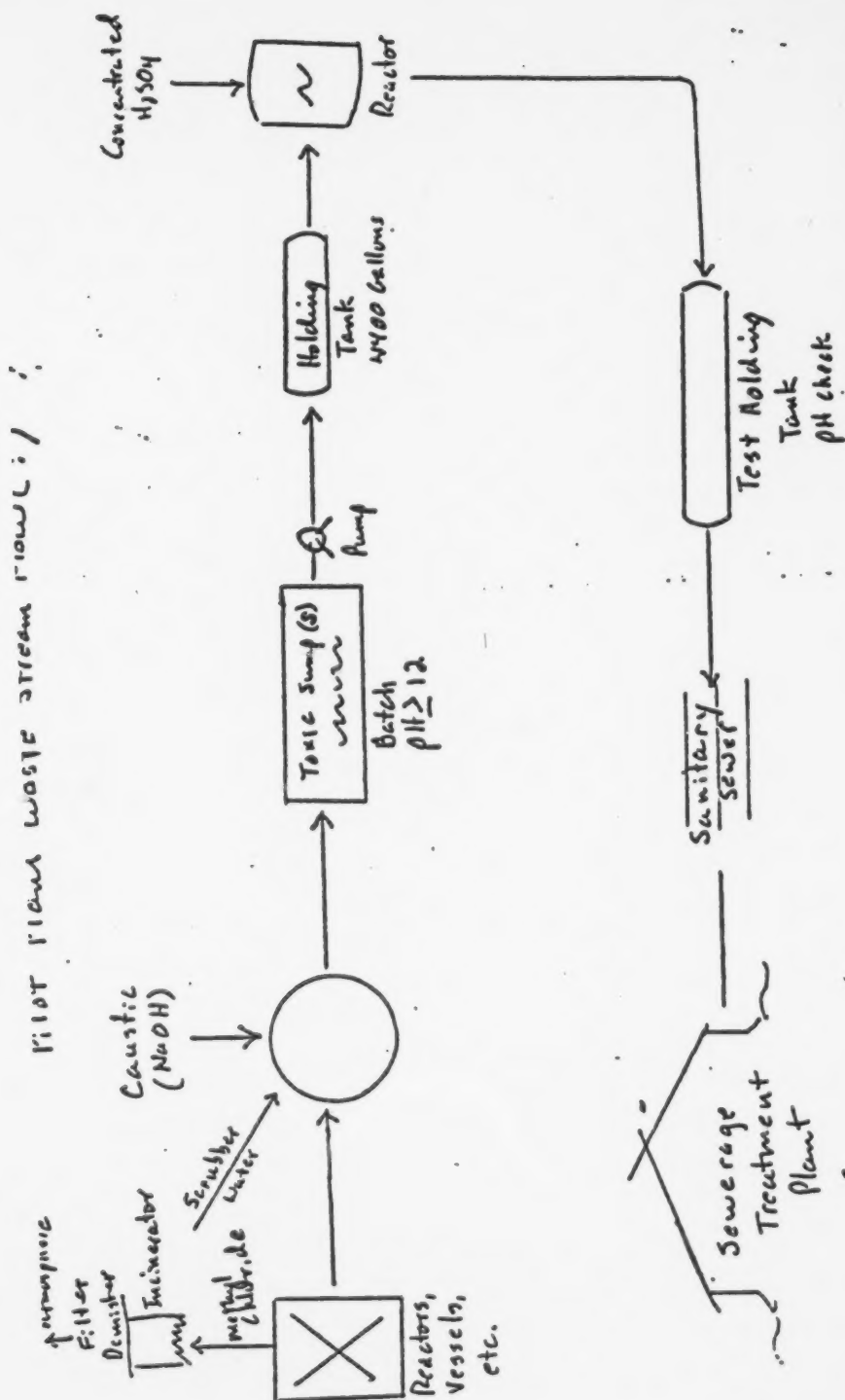
Waste Management Administrati
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EPA, Region III, Annapolis

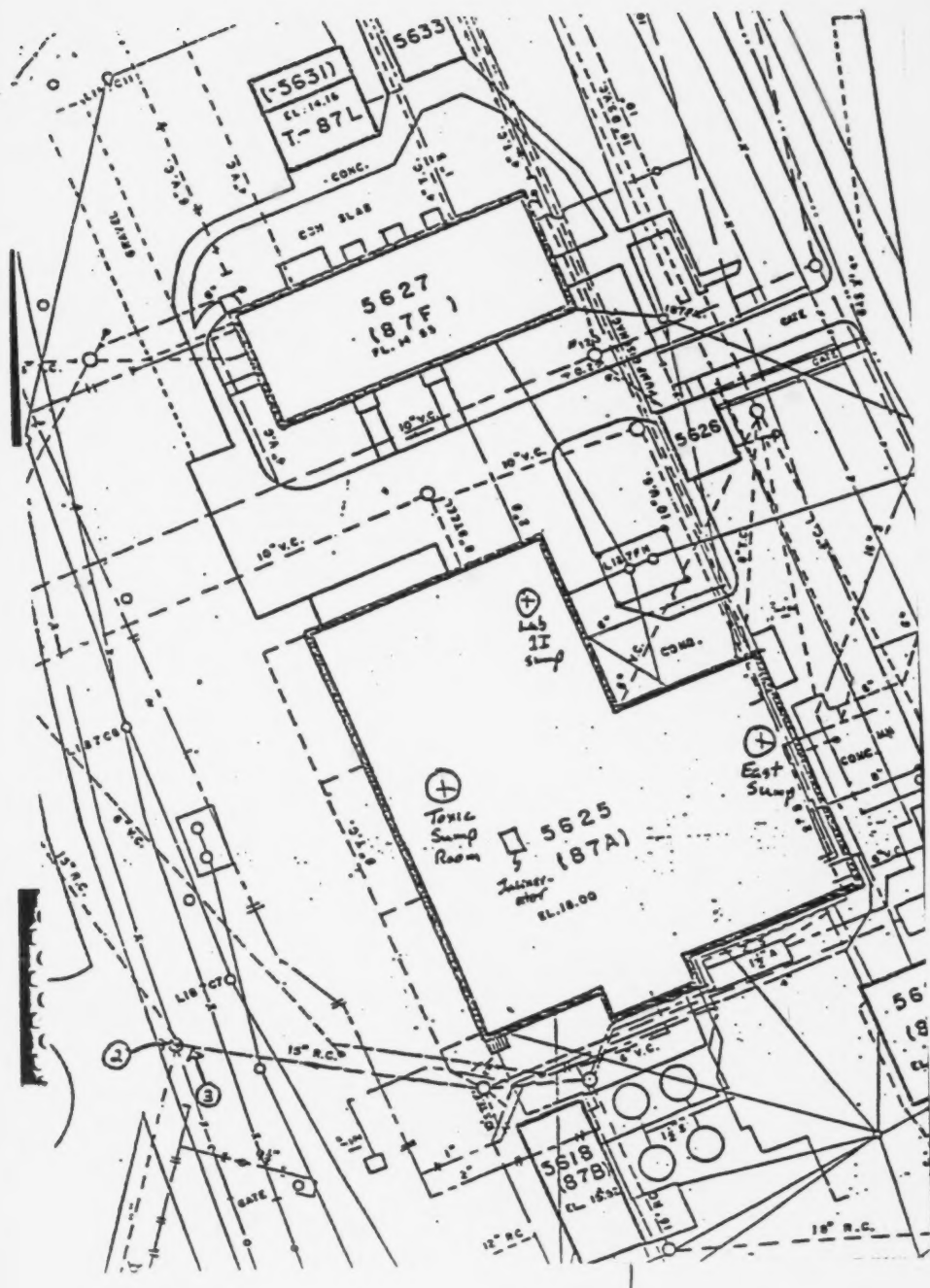
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Bob Lanaham
Steve Hearch
General Klugh
Colonel Durel
Hugh Riley
Terry Mann
Janis Chase
Jim Alingham
Carl Gepp
Bud Thomas
David Parks

Rosemary Austin

EPA, Region III, Annapolis
EPA, Region III
C.O., CRDC
CRDC
CRDC
CRDC
CRDC
CRDC, Public Affairs Office
CRDC Pilot Plant
CRDC Pilot Plant
APG Environmental Management
Office (EMO)
APG, EMO





ATTACHMENT C

STATE OF MARYLAND — DEPARTMENT OF HEALTH AND MENTAL HYGIENE

MEMORANDUM

Thru: John Koontz/Art Caple

 Copies: {
 Ron Nelson
 Paul Stancil
 Ed Hammerberg
 Don Andrew

TO Aberdeen Proving Ground From Butch Dye **BD** Date 3/11/86
 File
 Subject Pilot Plant Investigation

On Monday, March 3, 1986, this writer, Harold L. Dye, Jr., and Paul Stancil returned to Aberdeen Proving Ground (APG) for follow-up inspection and sampling at the Pilot Plant, Building 5825 at the Edgewood area of APG. We initially went to the Environmental Management office at the Aberdeen area of APG and met with Mr. Ken Stachiw and Ms. Rosemary Austin. Mr. Chuck Fisher, also of the Environmental Management office, talked with us briefly about the Pilot Plant. Mr. Fisher inferred that storm sewers under/adjacent to the Pilot Plant were very deteriorated. After advising Mr. Stachiw and Ms. Austin that we wished to return to the Pilot plant to tour the second floor and sample sump 1G, (a sump we were unaware of on our first visit), Paul and I drove to the CRDC security office for passes to the Pilot Plant. Ms. Austin met us at the security office and we proceeded to the gate at the Pilot Plant where we were met by Mr. Carol Gepp, Plant Manager (approximately 1015 hours, T.O.A. at Pilot Plant security gate). Directly inside the compound and adjacent to the guard shack, personnel from the Pilot Plant were pulling off the manole cover for a "sanitary sewer intercept" (see attached diagram). Steam was rising out of the manhole making it impossible to look down into the sanitary line to determine flow. Per Mr. Gepp, personnel were testing all sanitary lines in and around the Pilot Plant to determine where the lines flow and connect. (Use of latex paint to "dye" test lines). On other side of entrance road was another sanitary line with flow as indicated on attached diagram. No steam was emanating from this manhole.

We initially went to Mr. Gepp's office to discuss what we wanted to do and look at this day and to ask some questions about our observations during the 2/19/86 visit. Concerning the aqua blue water of the sump in "Lab 11", per Carl Gepp, the blue color was due to the titration effect of caustic on chrome thymol blue, an indicator added to phosphoric acid and water. Lab 11, at one point, was in use for a program in which simulants were made. Phosphoric acid was used as a simulant, drums of raw material were triple rinsed and poured into the toxic sump in Lab 11 (chrome thymol blue is originally yellow and turns blue in caustic; Mr. Gepp said that Hugh Riley reported that the split sample from the 2/19/86 visit was titrated back to an acidic

condition at APG's lab analysis office and it turned yellow). Odors from the Lab 11 sump room may have been due to the following compound's from APG's preliminary results of the Lab 11 sump sample analysis:

1-2 ppm	Chloroform
1 ppm	Benzene
1 ppm	Methylene Chloride
1 ppm	Acetone

Mr. Gepp advised that the capacity of the Lab 11 sump was believed to be approximately 3,000 gallons. No material will be transferred out of this sump until all lab analyses are returned. A steam jet ejector is built into the toxic sump system so that high pressure steam lines (90-110# pressure) will evacuate material to holding tanks and the reactor prior to neutralization. At this time, per Mr. Gepp, it is unknown how long the material has been in the Lab 11 toxic sump. He said that it probably was last pumped out five or six months ago. Only containers with 1/2" or less of materials are supposedly triple rinsed and the rinsate is dumped into the Lab 11 toxic sump. This may include a variety of materials in the rinsate. DMMP, a simulant, may be part of the rinsate. If a container has more than 1/2" of sludge in it, that material is supposedly consolidated into other drums for pick-up by the Environmental Management office. (Note: We did not verify this at the time of our visit and we did not ascertain at this time if records were kept of any CHS pickups from the Pilot Plant by the Environmental Management office). Mr. Gepp said that many different materials had been used here to develop simulants (such as grain alcohol, pepperdine/ethyl alcohol with phosphoric acid, and others). One operation of Lab 11 was to load hardware here and then ship the simulant or whatever to other areas of the country such as White Sands, New Mexico, for testing (field testing?). Other operations included the blending of materials and thickening agents and sending 55-gallon containers to the various sites where it was to be loaded into delivery systems. Sometimes, at Lab 11, materials were loaded into cannisters or delivery systems here, dependent on what test work was needed.

Responding to our questions about the sump, we called the "east" sump, Mr. Gepp stated that he is not sure what this sump is and that it is not a "toxic" sump as are the other sumps in the Pilot Plant. Lab analyses of the water sample showed it to have 50 ppm chloroform. At this point, Mr. Gepp advised us that on 2/19/86, he thought that we were going to sample the sump in Lab 1G, instead of the East sump (Lab 1G is adjacent to the east sump).

Conversation at this point turned to the second floor of the Pilot Plant. The second floor includes a machine shop, the "Custom Synthesis Lab", and various testing labs (2A, 2B, 2C, and

2D). Lab 2B is off limits due to it having contained B-1 dye, a carcinogen. Lab 2C has been placed off limits due to the surgeon general standards of 4 ppb limits for a particular agent tested in it. Analytical equipment can only detect the particular agent (unknown to us and probably classified information) down to 13 ppb. Therefore, although the lab was reported to have been decontaminated, it cannot be certified as clean due to analytical shortcomings. Lab 3C on the third floor and Lab 4C on the fourth floor are also off limits and padlocked per Mr. Gepp.

Following this meeting in Mr. Gepp's office, we proceeded to the Pilot Plant and up to the second floor (see attached diagram for approximate location of interior labs, etc.). Initially, we entered the machine shop which had various tools, hardware supplies, etc. From here we went to the "Custom Synthesis Lab", a rather cluttered "college chemistry" looking lab. Various types of classified research projects were ongoing in this lab when General Klugh told CRDC to discontinue operation at a certain point. Classified intermediate agent work was supposedly on-going.

(Note: There was one personnel working in this lab at time of our visit)

Per Mr. Gepp, all hooded lab equipment compartments drain into the 1G toxic sump, except for one compartment used in an experiment to turn diesel fuel into an oil fog used in obsurants, i.e., smokescreens (fog oil is carboxylic acid). The reason that this compartment has had drains sealed so that no discharge can go into the toxic sump is to prevent any volatiles from going into the sumps, per Mr. Gepp. The last hooded compartment was used to simulate off gas from manufacturing process to test elimination of salts (Pine Bluff, Arkansas, facility generates drums of salt that are disposed in landfills). Various lab sinks were noted in this "Custom Synthesis Lab". Per Mr. Gepp, these sinks presently drain to sanitary lines. Future plans are to divert wastes from lab sinks to toxic sump. Various jugs of materials were seen in this room with markings: organic waste November 1984, 2 methyl-2 butanone phenalcolone; organic phase via pivalic acid route; hexagon base pinacolyl alcohol; aminoethyl? (starting material for classified work); plus various bottles, equipment, vessels, etc., too numerous to itemize).

Outside of the custom synthesis lab in a small hallway between the lab and large hall were observed some containers with various chemicals and pipes, ductwork, etc. The custom synthesis lab atmosphere is constantly being purged through ventilation system.

From here we toured the area with Labs 2A, 2B and 2C. Lab 2A contained pipes, etc., from extension of other floor

activities. Lab 2B: High pressure soapy water was used to clean this room. When lab operations were in progress, everything was supposedly sealed off and all materials (wastes) were placed in 55-gallon drums. Lab 2C is the room that could not be certified clean. All of these labs were glass enclosed. Various vessels, equipment are inside. In the adjoining hall to these labs and adjacent to 2C, supplies of the membranes for lab 1B test units are stored. These membranes were used for "reverse osmosis" experiments which were used in support of removing hazardous materials from water so that troops are assured a supply of potable water. The reverse osmosis items are tested with nerve agent to check for their efficacy.

From here we walked over to Lab 2D, used for "hydrogenation experiments" among others. A hooded compartment was noted in here with various equipment, containers, and a container with "Ni5136R catalyst waste". Adjacent to this lab is a glass enclosed room that holds old process equipment. This glass enclosed room was, per Carl Gepp, "abandoned in place".

It was during this tour of Lab 2D that Mr. Gepp kept getting paged. At approximately 1155, Mr. Gepp got a call from Colonel Durel, who wanted to know why Paul and I were here and why no one had notified him as to our presence. Following Mr. Gepp's conversation with Colonel Durel over the phone, Mr. Gepp and Ms. Austin began to question Paul and I on where we got our information about the Pilot Plant. I advised them to call Bob Benjamin, if they had questions about his Baltimore Sun articles. Mr. Gepp said that he knew that there was a source in the Pilot Plant and that if there was any classified information being leaked out that the CID (Central Intelligence Division?) may be called in to investigate. I responded that my reports are given to my superiors and that if he has any questions on what information Mr. Benjamin may be obtaining, that he again talk to Mr. Benjamin. I emphasized that I do not talk to the press without permission from my superiors, and that all information concerning my investigations at this site must be given to my superiors before further disposition.

From here we proceeded to the first floor and Lab 1G. A meter outside recorded the toxic sump in Lab 1G as being approximately 45% full. Mr. Gepp said that the odors in this room may be caused by the processing around 4 years ago of a material known as Dimethyl Polysulfide (NM), some of which was discharged into the sump. Also, there might be some tear gas irritant residual in this room. An airlock was the entrance to this lab, and we did not go into this room without self-contained breathing apparatus. Adjacent to Lab 1G was 1H where "Chemical Hazardous Response Information" (CHRIS) work was done. This was a project sponsored by the U.S. Coast Guard. Some of the chemicals (bulk) came here and were broken down into smaller packages in this room so that they could be shipped to various

sites for whatever experiments would be performed. From here we walked around to the east sump to show Rosemary Austin where this was. The level of water in this sump appeared lower than it was on 2/19/86, although this could not be substantiated.

From here Paul Stancil and I proceeded to get our sampling equipment and don a level B type of protection. We obtained three 8 ounce samples from the Lab 1G sump, 1240 hours, by lowering a quart jar on a string into the sump liquid. No one came into this lab. Mr. Gepp stayed outside of the air lock. (Note: Dye tests being performed on lines outside of the room at this time). We detected no odors while using the self-contained breathing apparatus (SCBA) and did not attempt to remove the SCBA to try and discern odors due to safety concerns.

From here, we proceeded to the Lab 1I room still in SCBA. Mr. Gepp accompanied us into this room wearing no protective gear. He assisted us in sampling the 1I sump. Looking around the sump room, we noted containers of various materials, equipment, etc. Again, we took three 8 ounce samples from the sump. Adjacent to this sump room was a lab that Mr. Gepp said was a strict Level A room (fully encapsulated suit must be worn to enter). Naturally, we did not go into that room. Some of the markings on the drums in Lab 1I indicated: Ortho-2 methyl cyclohexane; air munitions, flammable, FMC. Adjacent to the exit/entry door of Lab 1I were various munitions (projectiles, rockets) cases that were supposedly empty of any compounds. These were examples of types of binary delivery vehicles.

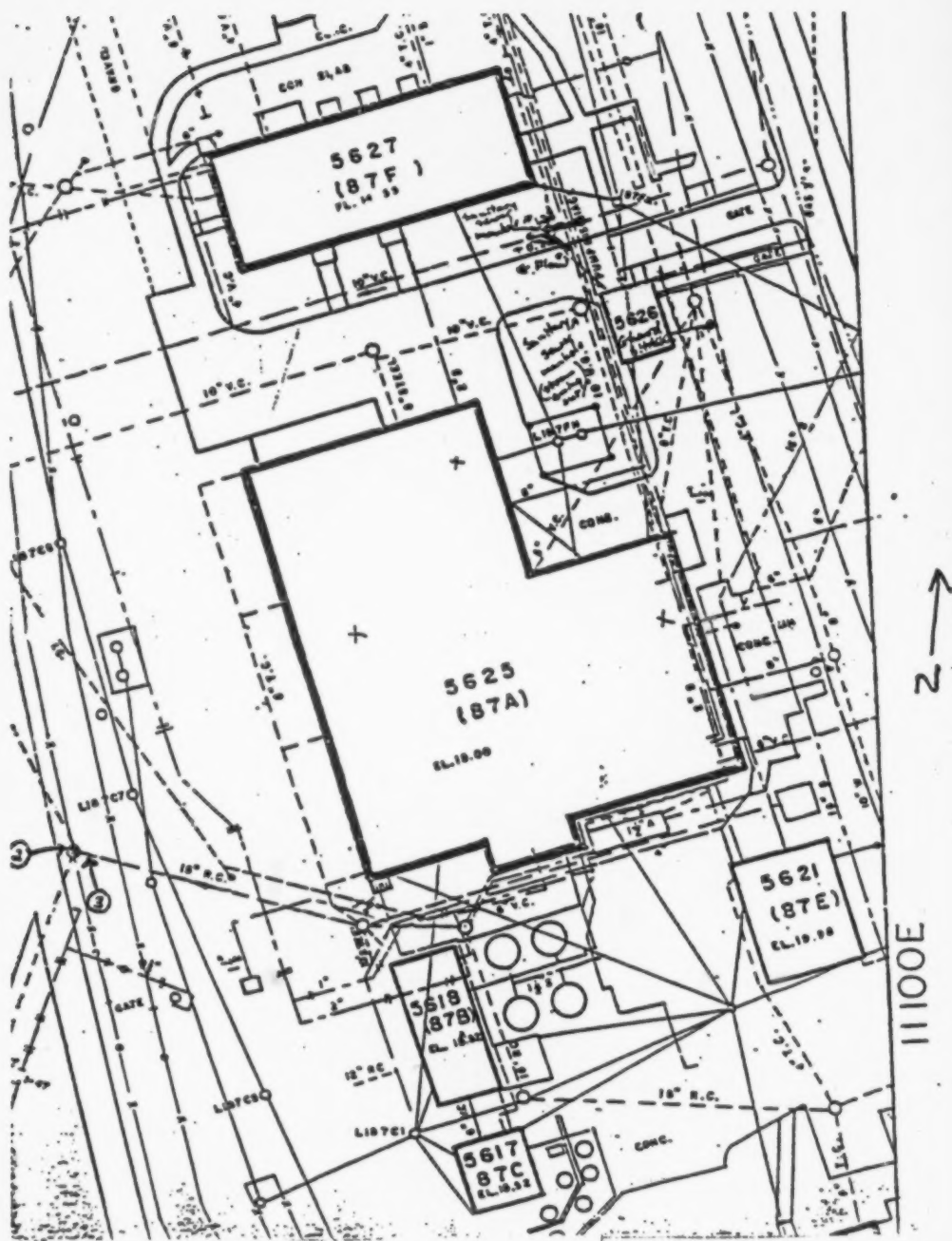
From this point, Paul Stancil and I exited Lab 1I, removed our SCBA's and Tyveks and proceeded to load the samples onto the truck.

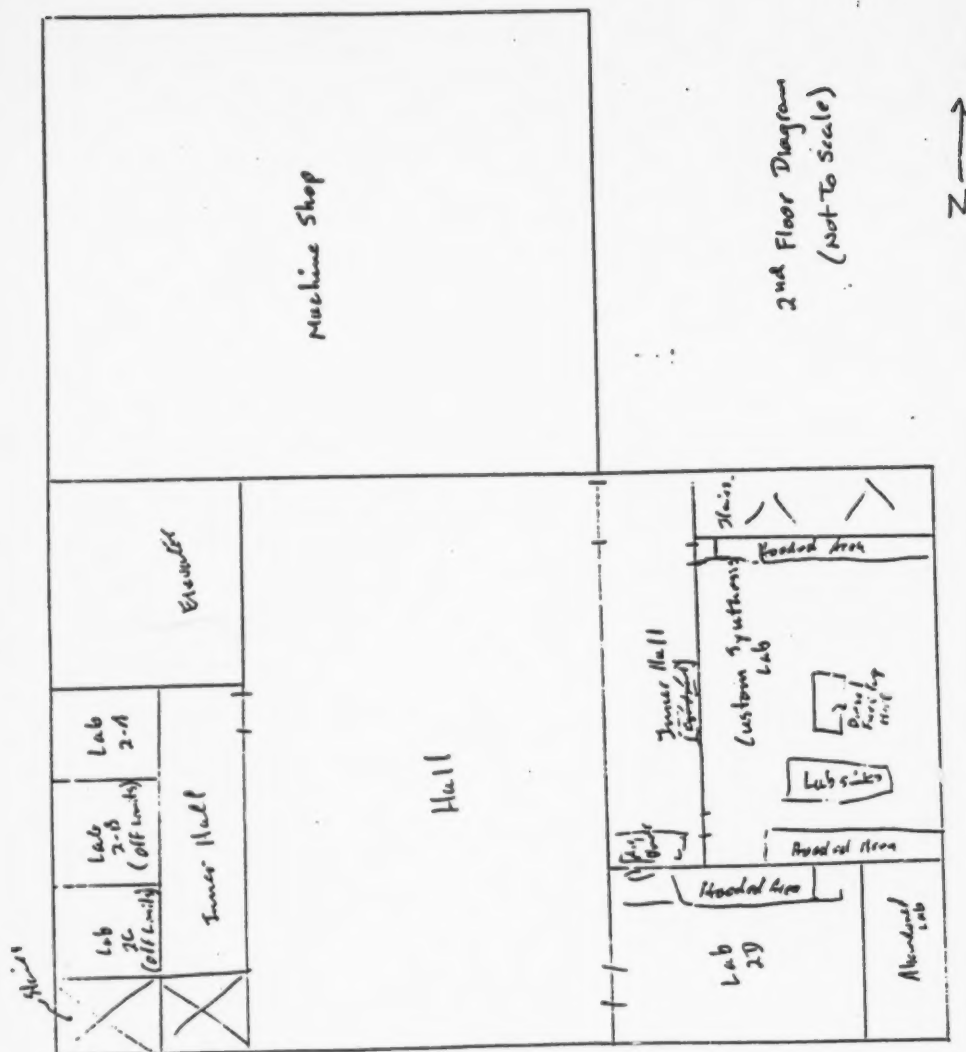
Rosemary Austin took one sample bottle from each of the sump samples. It should be noted that the samples from Lab 1G will represent a more "equal" split, as all three 8 ounce jars were filled from the same quart jar that was lowered into the sump. The samples from Lab 1I were obtained by using a glass colliwasa to fill each of the 8 ounce jars individually. I advised Ms. Austin that sampling from 1I may not have given the most ideal "split" conditions.

Following this, Paul Stancil and I left the site at approximately 1320 hours.

HD:d1

Attachment





ATTACHMENT D ()
STATE OF MARYLAND — DEPARTMENT OF HEALTH AND MENTAL HYGIENE

MEMORANDUM

Copies { Ron Nelson
Paul Stancil
Ed Hammerberg
Laramie Rude
Frank Courtwright
Don Andrews

TO Aberdeen Proving Ground From Butch Dye *BD* Date 3/21/86
File
Subject Joint AMA/WMA Inspection of Incinerator at Pilot Plant

This writer, Harold L. Dye, Jr., met with Ms. Laramie Rude and Mr. Frank Courtwright of the Air Management Administration on Monday, 3/10/86, in order to inspect the incinerator located in Building 5625, the Pilot Plant at the Edgewood area of Aberdeen Proving Ground (APG). The inspection was generated due to recent publicity surrounding the Pilot Plant and previous memos generated by the Waste Management Administration concerning operations in this building. Ms. Rude, Mr. Courtwright and myself met with Mr. David Parks of APG's Environment Management Office (EMO) and Ms. Terry Mann of Chemical Research Development Center (CRDC) at the CRDC Security Office to obtain access passes prior to going to the Pilot Plant. We arrived at the Pilot Plant entry gate at approximately 1100 hours and met with Mr. Carl Gepp, Plant Manager. As noted in memo for the 3/3/86 visit, plant personnel were checking the sewer lines inside the plant and around the perimeter of the plant. A storm sewer was found just in front of the guard shack and had been previously asphalted over. (See attached diagram) Per Mr. Gepp, the storm sewer line ran along the road. This storm sewer manhole is reported to be a storm sewer intercept. Mr. Gepp advised that from ongoing checks of sewer line, where any hazardous operations in the plant take place behind glass enclosed walls, or under hoods, wastes drains to the toxic sumps. All drains in the main hallway drain to a sanitary intercept outside of the plant. (See attached diagram) We looked down into the manhole of the sanitary sewer previously mentioned in the 3/11/86 memo (the manhole that had steam rising out of it and which blocked any visual inspection) and were able to see that the flow goes toward the above sanitary sewer intercept outside the plant. (See attached diagram)

Mr. Gepp explained to the group that Pilot Plant operations involved engineering studies for various projects involving compounds directly related to binary munitions programs. The function of the Pilot Plant was to scale-up from small research laboratory size to "Pilot" size. At this plant, 5, 10, 30, 50, and a maximum of 100 gallon reactors are used in various engineering experiments. All operating areas are vented, at some point through charcoal high efficiency particulate (HEPA) air filters. The continuous noise from the plant is due to the huge air blowers. A 100-gallon reactor, for example, will vent through a scrubber (after gas incineration, if applicable) and wet filters (5,000 cfm capacity filters). A pressure drop check

will be used to determine when any of the filters should be changed. I asked Mr. Gepp what the odor was in this area and he said that it was due to dimethyl disulfide (used in NM, an intermediate for a chemical agent), the odor from the Lab 11 sump and drums of NM.

It was at this point that I asked Mr. Gepp about the Lab 11 sump. Mr. Gepp advised that the material in this sump had been pumped to the neutralization reactor, neutralized, and transferred to the outside holding tank. I advised David Parks that I had spoken to Rosemary Austin by phone last week (Thursday, March 6, 1985), who wanted to know if the Waste Management Administration would give its approval for draining the Lab 11 sump and neutralization, due to the need for sump capacity because of drain line checks. I had responded to Ms. Austin that I, myself, could not give approval and that she should talk to the Waste Management Administration's Enforcement Administrator, John W. Koontz. (Mr. Koontz, who was in hearing range at the time of my phone conversation, said to drum the liquid in the sump as CHS). Per Dave Parks, Ken Stachiw, Environmental Manager, EMO, is alleged to have decided not to call John Koontz and to advise the Pilot Plant personnel to proceed with pumping out and neutralizing the Lab 11 sump material. The neutralized material is at the time of this writing being stored in the "after-neutralization" holding tank, and has not been discharged to the sanitary sewer.

The group proceeded into the Pilot Plant and went inside the glass enclosed room which houses the incinerator. (See attached sketch of incinerator/scrubber). The incinerator consists of the burner/chamber unit (approximately 7 feet high by 6 feet wide by 12 feet long) which exhausts through a quench pipe into a caustic scrubber (about the same size as the incinerator) where scrubbed gases exit to various filters and finally are exhausted to the atmosphere. There is an exhaust sample port after the scrubber. Per Mr. Gepp, samples are analyzed every hour when the unit is in operation. (Their procedure is to follow an 8-hour OSHA Time Weighted Average Limitation of 50 ppm Methyl Chloride. I asked Mr. Gepp if any other hazardous wastes or CHS were destroyed by the incinerator. Mr. Gepp replied that since he has been at the Pilot Plant (since about 1975) only one other disposal of non-routine (i.e., methyl chloride process gas is the routine gas incinerated) material was performed in 1979. The incinerator was used for a special biological incineration which comprised a 4-hour operation, and was observed by Mr. Gepp. No further details were provided and I assume further details involve classified information. Per Mr. Gepp, this incinerator had not been in use during 1985 except for performing routine equipment checks. Generation of methyl chloride gas is part of the operation on the third floor labs. Once the entire system was checked out, the process began to run in February 1986 for methyl chloride work. Wastewater during various checks of the system and the February work was drained to the Lab 11 sump. The chemistry is such that there are 2 moles of methyl chloride

generated for every mole of product. It takes approximately 2 1/2 hours to bring the incinerator/system up to proper temperature, approximately 6 hours for the process operations, and about 2 1/2 hours to cool the system down after process work is completed. The methyl chloride gas feed rate is actually controlled by the back pressure build-up in the third floor process reactors (e.g. dimethyl methyl phosphonate, DEMP, has thionyl chloride added to it in the reactor vessels. Possibly an exothermic reaction, whereby pressure that is built up is used as a force to feed the incinerator). Per Mr. Gepp, when this system was first set up and before Mr. Gepp was working at the Pilot Plant, there was nerve gas incineration ongoing for experimenting on the destruction of nerve gas. This took place, probably, during the early 1970's. Per Mr. Gepp, there are now, no surety agents in this building. The last surety operation supposedly took place in 1983.

[Note: There were "Use of Deadly Force" warning signs around this plant as late as the end of 1985. These signs were taken down, per Mr. Gepp, because no surety agents were in the building. I first noticed the absence of those signs during the 2/19/86 inspection of the Pilot Plant].

After breaking for lunch, the group returned to the Pilot Plant and Mr. Bud Thomas accompanied us on a further tour of the area (Mr. Gepp had another engagement during this time). I asked Mr. Thomas to show Mr. Courtwright and Ms. Rude the area where the acid leak had occurred last September. At the diked area, Mr. Thomas pointed out the various tanks in the compound. Only one of the "after-neutralization" holding tanks was being used as, according to Mr. Thomas, the other tank was found to have been leaking. I inquired as to when the leak had occurred and Mr. Thomas replied that he had only known about it a few weeks ago. (Later, at the post-inspection interview, Mr. Gepp advised that a small seep in the one tank was noticed during the time of the acid spill and the tank was removed from service. The amount of material that had seeped out, the type of materials, how long the seep had occurred before detection, and if any material was washed out into Canal Creek is unknown (see attached diagram for tank identification). Walking around to the east side of Building 5625 are large blowers and other machinery. In the center of all this is an open concrete pit. Various lines are in this pit ($\approx$ 6 feet deep). Adjacent to this was a small open pipe with, during our walk-through, some water discharging from another pipe into it. There were 2 apparent pumps on top of a metal cover adjacent to the pit. Function is unknown to me. We could see one line with openings in the top due to apparent corrosion. Mr. Thomas advised that this may be a steam condensate line, though he was not certain. (See attached diagram) Also, next to the plant was a door to a crawlspace under the plant. We did not go into this crawlspace.

We proceeded to the third floor where Mr. Thomas explained the function of the lab on this floor. For example, one of the 100-gallon reactors inside the glass enclosed room would exhaust

its gas to a packed column and reflux splitter up to the fourth floor apparatus. The unit generates SO_2 and methyl chloride gas, whereby the SO_2 is taken care of with a caustic scrub and methyl chloride gas is incinerated. Noted inside the third floor glass enclosed room were at least eleven jugs (approximately 5-gallon capacity) of "Dichloro bottoms". One 55-gallon drum of "Dimethyl Methyl-phosphonate" was observed. I asked Mr. Thomas what plans were for these bottoms and he replied that they may want to burn the bottoms as the bottoms react with water to liberate HCl gas. Or they will turn the material over to the APG-EMO for hauling out as CHS (by GSX?). Per Bud Thomas, GSX is picking up (for hauling to disposal sites) NM.

[Note: NM is reported to be one of materials in the steps for VX in a binary system]. Drums of NM are in the sandbagged, plastic covered storage area on the north side of the Pilot Plant. (From the 2/19/86 inspection, Mr. Hugh Riley had told us that the drums of materials in the plastic/sand bagged area were product/raw material. In the post-inspection interview, Mr. Gepp advised that 4 containers of NM waste were segregated from the other product/raw material containers).

[Note: See sketch. Four drums of NM against fence. Mr. Gepp said that the 4 drums had been outside for approximately 2 weeks. I advised Mr. Gepp that he should place the drums back in the plastic to ensure some containment for the 4 drums. Mr. Gepp said that GSX will be picking these drums up for disposal. GSX has picked up other waste materials. Liquids are put in smaller containers, pails, and sent to North Carolina for disposal]. The group went onto the roof on the third floor and observed several exhaust ducts, etc.

Following the tour, we met again with Mr. Gepp and discussed our observations. Per Mr. Gepp, the Pilot Plant is the largest operator of "equipment" at the Edgewood area. Other facilities performing agent work are only "laboratory" size and on a much smaller scale. Mr. Gepp and Mr. Parks advised that there are other tenant facilities having line testing performed and have neutralization and holding tanks. The Chemical Transfer Facility (CTF) Building has a chemical neutralization system with caustic sump, neutralization reactor similar to the Pilot Plant, but, as said before, on a smaller scale. Per Dave Parks, the CTF system is not in operation at this time due to some problems. Drums of waste generated at CTF go to the Decon/DeTox incinerator at this time.

[Note: Dave Parks had copies of correspondence between EPA and APG on incinerator permits/applications. We requested copies of this correspondence]. Following this meeting, we left the site.

HD:dl

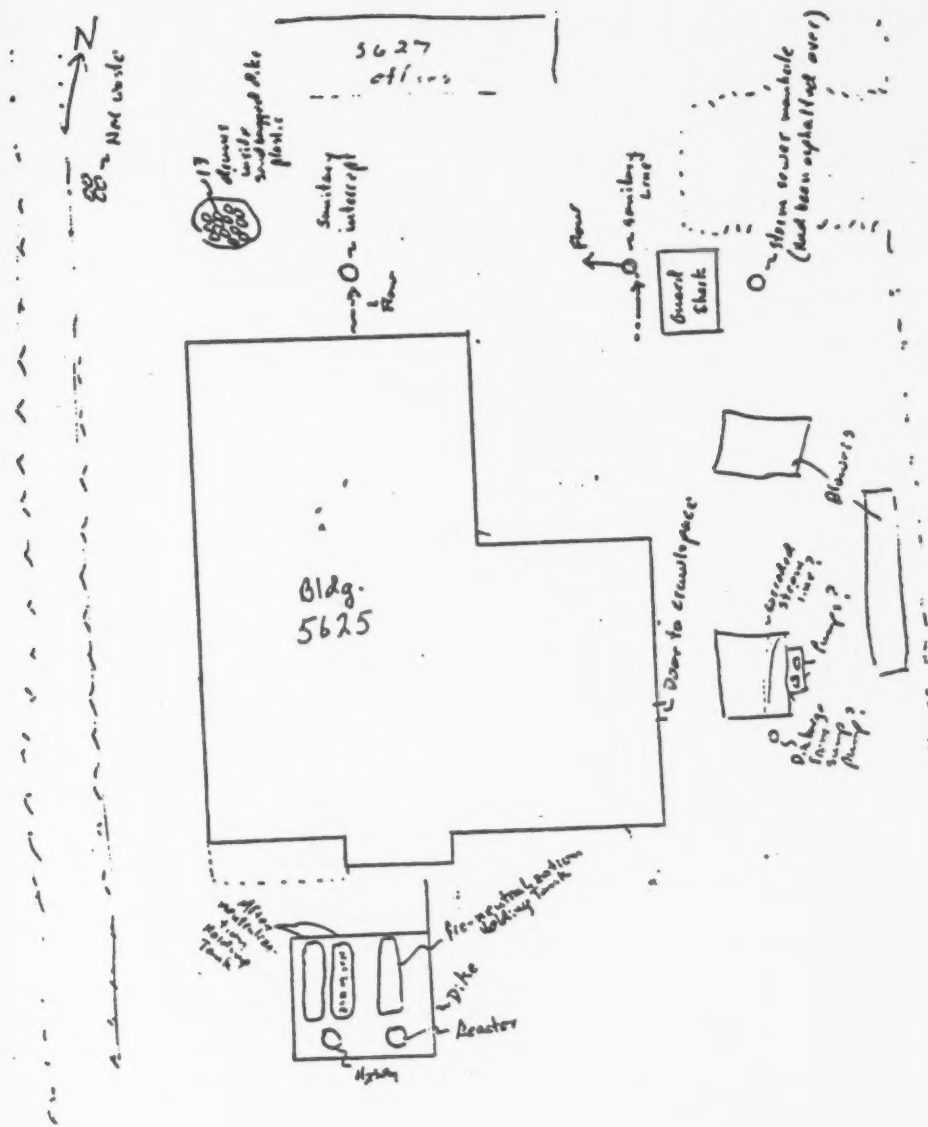
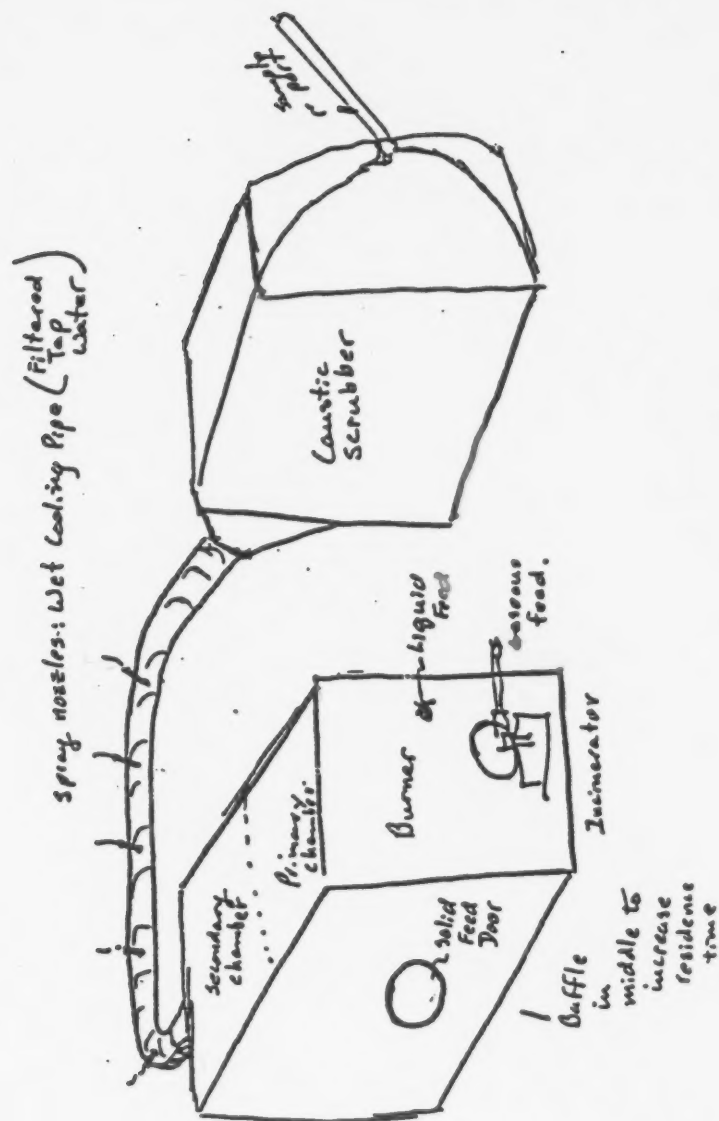


Diagram not to scale.
3-10-86



Drawing not to scale.

Pilot Plant Incinerator/Scrubber

ATTACHMENT E



State of Maryland
Department of Health and Mental Hygiene
Office of Environmental Programs
201 West Preston Street, Baltimore, Maryland 21201

Page 1 of 1

JK ✓

Report of Observations

Type of Inspection/Observations: Pilot Plant Investigation Date 4, 2, 86

Facility Name: Aberdeen Proving Ground / Edgewood Area

Remarks: This writer, Harold L. Dye Jr., received a call from the WMA Enforcement Administrator, Mr. John Kovacs, at approximately 2005 hours, who advised that he received a report that Edgewood Area was in process of removing/moving/relocating equipment and bulk chemicals to "proper storage areas" from Bldg. 5625, Pilot Plant. Mr. Kovacs advised me that Paul was in route to Edgewood Area of AFK and I advised that I would leave for Edgewood immediately.

I arrived at Edgewood Main Gate (AFK) at approximately 2035 hours, and was detained by security guards, who advised that they must contact appropriate personnel before permitting access to Edgewood Area and Pilot Plant. I spoke with Mr. Carl Gipp, Pilot Plant manager, who advised that they were in process of moving ^{off} process equipment and other items. He advised that I was not authorized to come into facility, per General Klugh and Major Lee.

I spoke with Major Lee & advised him of my purpose of being here. Major Lee advised that a conference would be held concerning this night's activities and other related items tomorrow, 4-3-86, at 0815 hours. I advised Major Lee that I wanted access to Pilot Plant this evening for observations, to which Major Lee said no access to site would be given. I advised Major Lee that I wished to speak with General Klugh and Major Lee advised that he would not give me General Klugh's phone number and again emphasized no access. I advised that I would write a DENIAL OF ENTRY on a Report of Observations at 2115 hours, 4-2-86.

Therefore, DENIAL OF ENTRY for purpose of observation of activity at Bldg. 5625, Pilot Plant, Edgewood Area, at 2115 hours, this day, Wednesday, 4-2-86. Advised Specialist Halavats of this form, and advised that he may or may not sign this form.

Observer:

DASH 1070

Person Interviewed:

Donald R. Delaney 2138 hrs.

Witnessed by Paul Stone!



State of Maryland
Department of Health and Mental Hygiene
Office of Environmental Programs
201 West Preston Street, Baltimore, Maryland 21201

INV
Page 1 of 2

Report of Observations

Type of Inspection/Observations: Pilot Plant Inspection Date 4/10/86
Facility Name: Aberdeen Proving Ground / Edgewood Area
Remarks: Representatives: Ms. Terry Mann, CRDEC
Mr. Wade Whitlock, Harford Co. Hlth Dept.
Mr. Chuck Fisher, ALB EMO
Colonel Francis Durel, Deputy Commander, 4802
Mr. Ed Hammerberg, WMA
Mr. Harold L. Dye, Jr., WMA

Purpose of visit was to inspect Pilot Plant area and generation of materials for disposal from peripheral buildings at Pilot Plant. Mr. Chuck Fisher had called Mr. Whitlock of Harford County Health Dept. on Wednesday, 4-10-86, and advised that ALB would seek permission to detonate chemicals found during cleanout of peripheral buildings that may exhibit explosive characteristics. (see attached list.) Other materials are also being removed and processed for "turn-in", disposal, reuse, etc. I have asked for a complete list of all materials in storage and removal from peripheral building of the Pilot Plant.

Following an initial meeting with Colonel Durel the group met at the Pilot Plant with Carl Gey and other personnel. Building 5633 is divided into an outside storage ramp and an enclosed area which has an entry door and a sign above it "Paint & Drum Storage". Lab bottles are in here along with small cans and ^{many} bottles outside. Unknowns and reactives are still in here. ^{outside} storage includes bulk materials as "solvent" storage (Picric Acid, Propyl Acetate, Isopropyl Amine, Triethylamine, Dibutylphosphate, Acetone, Antifreeze, among other containers with markings. ~~to show~~

We also toured the remainder of the peripheral buildings at the Pilot Plant area and found some rooms with miscellaneous lab bottles in process of inventory.

Adjacent to the office building was an area that

Observer: _____

Person Interviewed: _____

DHMH 3879



State of Maryland
Department of Health and Mental Hygiene
Office of Environmental Programs
201 West Preston Street, Baltimore, Maryland 21201

Report of Observations

Type of Inspection/Observations: Page 2 of 2 Date 4/10/86

Facility Name: _____

Remarks: had what appeared to be a large oil stain.
I took a sample of the soil and advised that I would
run the sample for PCB analysis. Against the office
building was a small metal bin that had been used
to store miscellaneous chemicals from some process. I
took a sample of sludge (appeared to be rusted remains
of metal cans) for organic analysis.

I have advised Colonel Durel and Terry Mann
that I would like to have copies of all inspection records,
safety inspection records and any related information on
inventories, etc. from building 5693 for the past 3 years,
and where the material came from (if from another site or
facility at Edgewood). (i.e. those generated from Pilot Plant clean

Any burning of reactives must be carried out
under the direction and permission of the State Fire
Marshall.

A meeting between CRDEC, APG-EMD and the
Waste Management Administration is indicated in order to
clarify positions on RCRA and responsibilities for each.
a and Harford County Health Dept.

A copy of this Report of Observations was
left with Ms. Terry Mann.

Observer: _____

DHMH 3672

Person Interviewed: _____

Terry Mann 10/9/86

225-5731

I split ~~some~~ samples with
Ms. Mann.

TESTIMONY OF NEIL H. LEVITT, PH.D.

My name is Dr. Neil H. Levitt and I am from Frederick, Maryland, and reside approximately two blocks from Fort Detrick. I received my doctorate in microbiology, specializing in virology, from Hahnemann Medical College in 1968. From 1969 to 1972, I served as a captain on active duty as a virologist-immunologist in the Virology Division at the U.S. Army Medical Research Institute of Infectious Diseases, followed by 14 years as a civilian research scientist in the same division until I resigned in February 1986.

I was a Principal Investigator responsible for the planning, conducting, evaluating as well as participating in research to develop methodology for the rapid diagnosis of viral diseases of man. From 1972-1979 I served as Principal Investigator and Team Leader responsible for the conducting of investigations into the development and standardization of in vitro techniques for studying the cell mediated and humoral components of the human immune system during virus infections.

From 1979-1985 I was the Principal Investigator and Study Director responsible for the planning, conducting, evaluating, while actively participating in research to develop live, attenuated and/or formalin inactivated vaccines for a variety of virus diseases of military importance.

I have lived in Frederick for almost 20 years, with my wife Carol, my son Cary (age 23) and my daughter Jamie (age 19). We have seen the city grow from an isolated farming community to a highly developed urban area, quickly approaching a population of 50,000 with a corresponding growth in the surrounding county.

We are very involved in our community and I am currently serving in my third four year term on the Frederick City Police Commission.

We own and operate two retail businesses in downtown Frederick and have invested in Frederick real estate and other local enterprises that benefit from the huge contribution that Ft. Detrick makes to the economic base of the community.

Along with the growth of the city, we have seen a tremendous growth in Ft. Detrick's Biological Defense Research Program, both in its Budget, and in the scope of its involvement with the most pathogenic organisms in the world.

During the 1960's and early 1970's the Army found it necessary to provide stringent security for the areas where its Chemical and Biological Warfare work was done. Military Police manned Ft. Detrick's main gates and mechanical barriers were opened after appropriate identification was produced. Once on post special clearance was needed to go "behind the fence" as the CBW research facility was known; again MP's and mechanical barriers and high barbed wire fence separated this area from the rest of the post.

Fort Detrick is now an open post and even though a high profile of security is maintained at the main gate, access to the post without any I.D. and without being stopped, is quite easy thru another entrance just a few blocks away on the other side of the post. Hundreds of people go in and out daily, including military, civilians, maintenance and construction workers.

Detrick once surrounded by quiet rural roads and farmlands,

is now surrounded by highly populated housing developments, shopping centers, schools, heavily traveled roads and air corridors, and, the BDRP continues to work with the most highly infectious and deadly organisms in the world.

From 1977 to 1985 my mission was to develop and produce a live, attenuated Chikungunya virus vaccine for human use. Chikungunya is a highly infectious virus spread by mosquitoes and currently on the U.S. Army's biological warfare threat list. By the summer of 1985, we developed and produced 3 lots of vaccine which passed all Food and Drug Administration (FDA) safety requirements. The vaccine is presently being clinically tested in human volunteers at USAMRIID. Unfortunately, several disturbing and highly irregular events occurred during those years that I feel should be brought out at this time.

In June 1980, I was instructed to prepare an experimental vaccine in certified Fetal Rhesus Lung cells, a cell line used previously by the Army to produce four separate Dengue virus vaccines - all of which were subsequently scrapped because all four viruses reverted to wild type after inoculation into volunteers. The Chikungunya vaccine we prepared failed preliminary FDA safety testing and, most importantly, the fluids from the Fetal Rhesus Lung cells killed two-thirds of the suckling mice tested. This finding was corroborated by an independent lab at the Salk Institute in Swiftwater, Pennsylvania. This finding, together with subsequent results, indicated a serious if not dangerous problem existed with these cells - which I reported both orally and in written reports. In

the Fiscal Year 1981 Annual Report, I discussed the problems we observed with this cell line - with my recommendation that it not be used for human vaccine production until additional studies were performed by expert cell biologists. However, these results and recommendations did not appear in the version sent to Congress - quite the contrary, only a glowing report of the vaccines progress was discussed. At this point, I refused to use these cells for vaccine production and switched to another cell line (MRC-5) for the remainder of the vaccine's development.

Although the contamination problems encountered with Fetal Rhesus Lung cells were common knowledge in the Institute, a Junin virus vaccine was developed and produced in these cells and is presently being tested in human volunteers at USAMRIID. I am now recommending as I did then - that the Fetal Rhesus Lung cell line be examined extensively for contaminating organisms or latent viral genetic material, using all the sophisticated techniques presently available.

In July of 1981 a fire broke out during the pre-dawn hours in the Biological Development Suite at USAMRIID. It was determined that the cause of the fire was a faulty, ultra-low temperature freezer containing a previously determined hazardous mixture of pentane and freon which was ignited by a spark in its electrical system. This type of fire was previously observed in another Detrick laboratory. There were no fire or smoke alarms in the suite. The fire was detected by the early arrival of an employee who smelled smoke in the hallways.

After being notified, the Fort Detrick fire department went directly into the suite with equipment to extinguish the fire, without regard to the biological hazard of the suite. The suite and airlock doors were propped open and water ran out of the suite and into the hallways. Detrick personnel wandered in and out during the confusion, and from that time on, and without any decontamination procedures, the lab was considered "cold" and special safety precautions no longer applied.

Freezers containing virus samples were taped shut and all work ceased in the lab for six months while management deliberated over who would clean up the fire damage.

Laboratory fires are not uncommon, due to the nature of equipment and chemicals used in lab procedures. A recent example is the laboratory fire at the Drug Enforcement Agency in Washington just a few weeks ago. Unfortunately fire drills at USAMRIID were never taken seriously and safety drills were nonexistent.

During a routine inventory of virus stocks in September 1981, I discovered all the Chikungunya virus, grown in Fetal Rhesus Lung cells, was missing from an ultra low-temperature freezer in the Bio Development Suite of USAMRIID. It was immediately reported to Department and Division chiefs who subsequently confirmed the disappearance of approximately 60-70 various sized vials containing almost 2500 milliliters of virus, with each milliliter having a concentration of over one billion virus particles. No meeting or formal investigation was ever initiated although I requested one on numerous occasions to both

my immediate supervisors and the USAMRIID Safety Officer. After three months of requesting administrative action and receiving none, my colleagues, including management level personnel, and I composed and signed a Memorandum for Record which documented a series of untoward events leading up to the mysterious disappearance of the Chikungunya virus. Copies of the memorandum were sent to the Safety Officer and other administrative offices. To date, no satisfactory answer to how or why the virus disappeared or where it is, has ever been offered. It is obvious that serious safety and security breaches occurred which were exacerbated by the lack of action taken by the USAMRIID command and Safety Personnel. What makes this event, even if it is, an isolated event, so disturbing, is the fact that the missing virus material possibly could have impacted serious consequences on the surrounding environment.

An investigation in 1986 by the Pentagon, initiated at my request by former Senator Charles Mathias, confirmed that the disappearance of the virus was not reported to a higher command and that USAMRIID had no written procedures to handle such occurrences. (See attached memo)

During a meeting with a member of Senator Levins Staff in late 1986 I discussed the issues of safety and security at Fort Detrick and the other contract laboratories in the BDRP. At this time I related these incidents of safety and security problems that were also addressed in a lawsuit brought against the Department of Defense by, Jeremy Rifkin, the Foundation on Economic Trends, and myself. The out of court settlement

required the DOD to produce an Environmental Impact Statement on the DOD's BDRP. The lawsuit and the resulting draft EIS have focused a great deal of public attention on these issues and hopefully will bring about much needed changes.

The lawsuit brought public attention to the fact that the US Post Office and other mail carriers were handling biologically hazardous materials.

The following are some of the additional security safety and environmental problems I feel still need to be addressed.

USAMRIID recently installed a new security system of magnetic I.D. cards to reduce the possibility of unauthorized personnel from entering high containment laboratories. However this does not address the issue of unauthorized removal of biological material from the suites. During my tenure at USAMRIID there had never been to my knowledge, a physical inspection of briefcases, bags or parcels being carried in and out of "hot" suites.

The institute did not have a complete accounting of what quantities of biological organisms were on hand at any given time, since routine inventories were not mandatory and researchers have a lot of latitude in this area.

Technicians and researchers including management level personnel have been known to breach security by going in and out of hot suites without changing or showering out.

Technicians come to the BDRP right out of Army training camp most have no lab or scientific experience. It was up to the investigator that he or she is assigned to provide on the job

training. There were no formal mandatory lab safety training or character screening programs for these people and yet they were often left alone to perform many lab tasks involving highly pathogenic organisms and delicate expensive equipment. When breaches are observed in laboratory safety by scientists at USAMRIID, they are powerless to make changes without approval from administrative personnel, which is usually preceded by a lengthy bureaucratic process.

In 1978 while working under a biological safety hood I was exposed to high doses of Radioactive Iodine which was subsequently detected two weeks later by a routine thyroid scan. This exposure was later determined to be caused by a malfunctioning hood which blew the Radioactive experimental material into my face instead of exhausting it up into the hood. If routine maintenance procedures had been performed monthly this accident might never have occurred. Even after this accident I repeatedly had to request safety checks of the hoods rather than having it routinely performed by safety personnel.

From the early 1970's to the present, problems with USAMRIID's Biological Development suite's ventilation system have been documented. Workers suffered from a variety of ailments caused by design problems. Fungus and mold caused allergic reactions and lung infections. Diesel fumes and other chemical odors including paraformaldehyde caused burning itching eyes, sneezing, coughing, shortness of breath, headache, rhinitis, dizziness, disorientation with possible long term effects.

Decontamination of equipment using paraformaldehyde was a

procedure that was only supposed to be done on weekends so that fumes would dissipate by Monday morning work hours. It became common practice to do this procedure mid-week without warning and label it as an emergency procedure. After years of complaining signs were posted, reading, traces of paraformaldehyde may be present. Gas masks were issued by the Safety Officer to personnel that complained. Laboratory workers should not be expected to perform highly hazardous work under these adverse conditions.

In conclusion I have submitted to you my observations and experiences in the DOD's BDRP.

Ft. Detrick has made great contributions to medical research and has been the model for safety and security in the Scientific Community. However, if lapses and breaches in safety and security still surface at Ft. Detrick then it can be assumed that the problems are much more common in labs throughout the rest of the BDRP that don't have facilities equal to Detricks and where the military does not have the resources to monitor these programs in a meaningful way.

The priorities of the program need to be re-evaluated with more emphasis on US public health and welfare both in medical research and safety and security.

In the case of Ft. Detrick the highly hazardous elements of the BDRP have grown too large for a city that has grown too large for it - to risk an accidental release of deadly organisms for the sake of trying to defend against an indefensible weapons system would be devastating and unforgiveable.



DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
FORT DETRICK, FREDERICK, MARYLAND 21701

DA FORM 100-10

SGRD-UIV-1

30 December 1981

SUBJECT: Untoward Occurrences in Bio Development Suite 1.

MEMORANDUM FOR RECORD

1. It has occurred to the undersigned that a whole series of events in Bio Development Suite 1 have been reported only verbally to Chiefs, Virology Division and Viral Pathogenesis and Immunology. Since memories fail, we feel that the facts should be stated in writing and be part of a permanent record, thereby, serving as a point of factual reference if questions should arise in the future. The events in question occurred between September 1980 and September 1981. The events that an individual can personally attest to will be initialed by that person.

2. The most significant occurrences are as follows:

a. During the course of a freezer inventory by Mrs. Ramsburg on 8 September 1980, it was noted that a vessel containing 350 ml of Chikungunya vaccine (see Notebook No. 1452, p. 16, for specifics) was missing. She immediately informed Drs. Cole and Levitt who subsequently informed COL Eddy and LTC Peters. For specifics of inventories see pages 16 and 17, notebook No. 1452.

b. During February 1981, tests were performed for adventitious agents in the pooled control fluids from the vaccine run described above. It should be noted that these control cultures were handled prior to the vaccine flasks. Results in our laboratory demonstrated the absence of Chikungunya virus, although some adventitious agent was present. Work sheets are available to support this data (23 February 1981). Samples of this material were sent to Salk for confirmation of these results. As indicated in their letters of 27 March 1981 and 12 October 1981 (see inclosures), our results were indeed confirmed. Upon retesting here, the control fluids were found to contain $10^{8.5}$ PFU of Chikungunya virus as demonstrated by neutralization tests. (See work sheets dated 11 and 17 March 1981).

c. In early September 1981, Mrs. Ramsburg discovered that the freezer (Ravco) containing seeds and clones of Chikungunya virus was no longer maintaining temperature. This freezer had been sealed with tape after a laboratory fire (17 July 1981) which halted research in the Suite. She noted that the contents of the small vials were thawed. Mr. Hasty brought Mr. Carroll Shultz, refrigeration technician, into the Suite to examine the freezer at that time. Mr. Shultz determined that although the freezer was in perfect working order, the rear caliper type temperature control knob had been changed from -60° to 0° C. Only a concerted effort could bring about a sufficient number of turns of a caliper type dial to effect such a large change in temperature setting. It should also be noted that although this freezer was connected to the building alarm system, it did not function.

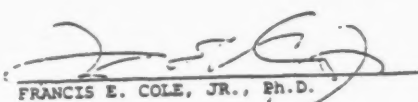
SGRD-UIV-1

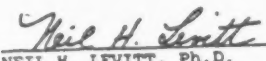
30 December 1981

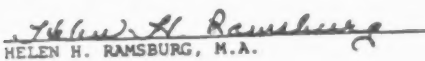
SUBJECT: Untoward Occurrences in Bio Development Suite 1

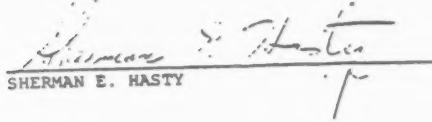
d. The most significant and disturbing occurrence was discovered by Dr. Levitt on 16 September 1981 while taking a freezer inventory (Calumet SN69483). It was noted at this time that all of the Chikungunya vaccine and production seed was not in the freezer in which it was originally placed. Neither could it be found in any of the other freezers in the Suite. COL Eddy was immediately notified of the missing vaccine. He came directly to the Suite and examined the freezer with Dr. Levitt. LTC Peters was subsequently informed of 2352 ml of missing vaccine, production seed and control fluids. During a subsequent conversation with Mr. Hasty, he remarked that he had noticed space in this freezer two weeks prior to the discovery.

Incl
as


FRANCIS E. COLE, JR., Ph.D.


NEIL H. LEVITT, Ph.D.


HELEN H. RAMSBURG, M.A.


SHERMAN E. HASTY

CF
COL Eddy
LTC Peters
Mr. Kuehne

TESTIMONY

of

LEE LUCAS BERMAN and THOMAS V. GAUDIOSO

on

HEALTH AND SAFETY AT YALE UNIVERSITY

before the

SENATE GOVERNMENT AFFAIRS SUBCOMMITTEE

on

OVERSIGHT OF GOVERNMENT MANAGEMENT

July 27, 1988

Mr. Chairman and members of the Subcommittee:

My name is Lee Lucas Berman. For eleven years I was employed as a Research Assistant at the Yale University Medical School, Department of Epidemiology and Public Health (EPH). I worked on the ninth floor of the building which houses the Yale Arbovirus Research Unit (YARU), providing technical support and eventually overseeing the laboratory of a full Professor of Epidemiology. In these capacities I handled many infectious agents and witnessed as an employee the workings of the University's biosafety program. For the majority of those years, I was a member of the EPH Health and Safety Committee, a representative group of faculty, staff, and students. We regularly discussed issues of safety in the department, and made recommendations for improvements in policy. During my years as an employee in EPH, I frequently interacted with the Principal Investigators who administer the DOD-sponsored grants in question here today, Dr. Robert Shope and Dr. Gregory Tignor. I must state that I have had nothing but positive, professional and courteous relationships with them, and do not mean this testimony to demean in any way their personal or professional integrity.

With me here today is Thomas V. Gaudioso, President of Local 35, representing the service and maintenance employees at Yale, such as custodians, tradespeople, and grounds maintenance employees. Both Locals 34 and 35 are affiliated with the Hotel Employees and Restaurant Employees International Union. Mr. Gaudioso was a Gardener for fourteen years in the Grounds Maintenance Department, the last three of which were at the Yale Medical School. A sincere concern for the health and safety of his fellow employees resulted in his continuing involvement in

the Union. He has served as a member of the Health and Safety Committee with Local 35 for five years, and has since November of 1985 been President of Local 35, an elected, full-time Union position. In that capacity Mr. Gaudioso represents the custodial and maintenance employees who service the Department of Epidemiology and Public Health.

We are presenting this testimony today because we believe that the issue of safety in Department of Defense-sponsored research laboratories, at Yale or elsewhere, is a matter of public concern. The question of safety and health within the Yale Arbovirus Research Unit has potential effects not only on the scientists in its laboratories, but also upon: secretaries in adjacent offices, lab aides who sterilize the glassware, custodians who mop the floors, maintenance employees who service the equipment, staff members on adjacent floors, in adjoining buildings...and even perhaps on the entire New Haven community at large. We're concerned. We're concerned for everyone's safety. And that's why we're here.

In citing the following examples of recent health and safety problems at the University, we hope to illustrate these points:

1. The Yale University administration is not totally unresponsive to employee concerns. Many sincere efforts have been made to address safety problems at Yale, and many improvements have been engineered in recent years.
2. However, the Department of Occupational and Environmental Health at Yale, as currently staffed, is inadequate to the task of maintaining a healthy and safe environment in as diverse a place as a major University, and

3. Adequate preventive measures (most specifically in the area of training) could have averted most, if not all of these incidents.

MAJOR HEALTH AND SAFETY PROBLEMS AT YALE

The following recent incidents could have had serious effects upon employee health. Although these particular events did not occur in YARD, they did happen in an adjacent building, connected by a pedestrian tunnel.

The first was an explosion in Sterling Hall of Medicine, caused by the improper storage of iso-pentane in a laboratory refrigerator. The explosion, which happened at 1 a.m., was serious enough to have blown the refrigerator's door approximately 25 feet into an adjacent laboratory, as well as to have sprung the hinges on a very heavy metal door-frame. The University (in the person of Larry Gibbs, former Director of Chemical Safety) responded quickly to employee concerns. An informational meeting was held, a written description of the incident was disseminated with warnings about chemical safety, and an inventory was begun of explosion-proof refrigerators. This after-the-fact response on the part of the University was not unreasonable. Yet it cannot negate the fact that no one in the lab, nor in any of the University's other 1100 research labs, had received training sufficient to have prevented this accident. The response, though reasonable, cannot negate the fact that an effective chemical hygiene program, which would include training, inventories, and monitoring of the handling and storage of hazardous chemicals, might very well prevent needless accidents in the future. This explosion occurred in the laboratory of the chairperson of a Medical School Department. Even this principal investigator admitted that he had improperly

stored the chemical for at least five years, because he had never been told not to.

The second incident was a radiation spill, also in the Sterling Hall of Medicine. A relatively small amount of a radio-isotope was spilled, apparently over a weekend, in a common glassware washing facility. A lab aide (Local 34 bargaining unit), while mopping up after a dripping autoclave, inadvertently spread radiation all over the floor. Then, apparently, an equally unsuspecting custodian (Local 35 bargaining unit) mopped more contaminant along hallways and into offices and labs. By the time of detection, the substance had spread to stairways, labs, offices, a conference room, lavatories, and even into the Yale Child Study Center, which was publicly accessible through the contaminated hallway. Again, the University's response was reasonable. The spill was cleaned up quickly, and the University agreed to the Union's proposal to offer training in radiation safety to the lab aides and custodians, as well as to clerical and technical workers in the department. They also agreed to increased surveillance by the Department of Radiation Safety.

Within the last two years as well we can cite the Yale administration's response to a spill-over from a legionella-contaminated cooling tower, precipitated by the addition of a biocide by a Physical Plant employee. This incident prompted an agreement by the University to hire a chemical company to test and maintain all campus cooling towers in the future. And the unsuspecting bare-handed clean-up by a secretary of the blood of an AIDS patient prompted an immediate agreement providing for mandatory training of all employees in the Yale Health Services Center. About five years ago a custodian was pricked in the leg by a needle which had been disposed of improperly in the trash. The injury resulted in an infection which caused her to be laid up for months. Numerous other incidents such as this one prompted the University's implementation of a sharps disposal

program so that sharp equipment such as needles and pipettes would be disposed of in a safe manner.

Four years ago, in EPH on the ninth floor, three hamsters infected with Creutzfeldt-Jakob (C-J) disease virus (a degenerative disease of the brain) disappeared from a high containment animal facility. It resulted in furor among department employees and students who had not suspected that the facility existed.

We point out these incidents because conditions such as those that gave rise to such incidents exist in many biohazard labs at the University, including within YARU. In YARU, radioisotopes are used, flammable solvents are stored, animals are employed, and blood products and infectious agents abound.

PROBLEMS IN HEALTH AND SAFETY RELATED TO YARU

Concerning the research that is performed at the Yale Arbovirus Research Unit, a number of concerns have been raised by employees and others working in or near the facility:

1. YARU encompasses the sixth and seventh and some of the eighth floors of the Laboratory of Epidemiology and Public Health (LEPH) at the Yale School of Medicine. The first four floors of LEPH contain offices and classrooms utilized by students and faculty at the School of Public Health. Each September a couple of hundred students descend upon the building. They ride up and down unsuspectingly in elevators which, although they bear the warning: "No unauthorized persons allowed above the fourth floor", travel to whatever floor beckons. Most of the virus laboratories from the fifth

floor up (including YARU), though posted with biohazard signs, are not locked and are easily accessible.

2. Security in LEPH is difficult if not impossible to maintain. Access to the building through the front and back doors requires a key or I.D., but one can freely enter the building through a pedestrian tunnel, and from a loading dock. Underground pedestrian tunnels connect a network of buildings in the medical area at Yale, covering approximately three city blocks. The network includes the Yale-New Haven Hospital, the Yale School of Medicine and various clinic facilities. Theoretically, access to these buildings is controlled. In reality, access to LEPH from any of the other buildings is not monitored.
3. In general, the University has been remiss in providing training in health and safety to other than technical staff; in YARU the situation is no different. Custodians who empty trash containers and clean floors have never been told of the specific hazards associated with the position, nor do they feel that they have been adequately trained to work in a facility such as YARU. It was reported to us recently that the custodians sometimes find orange biohazard bags (to be used solely for the disposal of biohazardous material) in the regular trash, with no indication on them as to whether or not they've been decontaminated. Custodial and maintenance staff fear for their health, a situation which exists primarily because of lack of information and training.

4. A recent incident resulted in illness in a YARU employee. A professional employee, while working with the Dengue virus, contracted the disease. This points out the need for training even among professional employees at the University.

5. Robyn Gershon, during her tenure as Director of Biological Safety at Yale, had implemented the first systematic program for vaccinating employees against biological agents and monitoring employee needs. It was our sense for a few brief years that the responsibility of monitoring employees' vaccine status was finally out of the hands of the employees, and in the hands of the Department of Occupational and Environmental Health where it rightly should be. Since Ms. Gershon's departure, one and one half years ago, that momentary sense of security has lapsed. Perhaps there is just a lack of communication, but not knowing causes fears.

6. Another issue of concern to employees within the past year was the suggestion by Dr. Robert Shope that Physical Plant employees be vaccinated against Venezuelan Equine Encephalitis, with which he planned to work in the eighth floor animal facility. The Director of Physical Plant recommended that all employees be vaccinated, in case any one of them might be called in for repairs. VEE vaccine is an experimental live virus vaccine, distributed by the U.S. Army, requiring the signing of a consent form before administration. Most workers were nervous; some refused the vaccine; at best, all were confused. In a meeting between the Unions and the University it was agreed that only a small team of workers would require

the vaccination, and that no one's employment would be jeopardized for refusing the vaccine. On further investigation, we found that the vaccine protocol, which required the use of human subjects for research had not even been submitted for approval by Yale's Human Investigation Committee. The project was suspended, at least temporarily.

7. Also during Robyn Gershon's tenure at Yale, she implemented a program of inspections of biohazard labs. Each year she performed a detailed inspection of each of the approximately 350 labs in which biohazards are used. Although once yearly is not adequate, at least the workers and the community had the sense that someone was watching. To our knowledge, no inspections have occurred in the one and one half years since Ms. Gershon's departure, and perhaps even longer, until very recently.

UNIVERSITY RESPONSE TO GOVERNMENT LIVERSIGHT

The Department of Occupational and Environmental Health at Yale is responsible for overseeing the Divisions of Radiation Safety, Biological Safety, Chemical Safety and Employee Health. In only one of these, Radiation Safety, is there substantial Federal regulation. It's interesting to note that of the total Department of Occupational and Environmental Health staff approximately half are employed by the Department of Radiation Safety. In striking contrast to Radiation Safety's sixteen employees is the staff of Biosafety, with three staff members.

Clearly federal regulations elicit response from the Yale administration.

Indeed, even this subcommittee's investigation has prompted the first laboratory inspections in one and a half to two years. And a visit from the Nuclear Regulatory Commission after the radiation spill no doubt added to the University's willingness to implement necessary training programs and surveillance.

CONCLUSION

As Union Health and Safety representatives, we have had the opportunity to observe first-hand the workings of Yale's Division of Occupational and Environmental Health. We have watched person after well-meaning person laboring under the continuing frustration of being provided inadequate resources with which to properly do the job. The function of the Department of Occupational and Environmental Health in the recent few years, has been an exercise in crisis management.

The Unions at Yale have been diligent in their quest to hold the University accountable in matters concerning safety and health of Yale employees. We have incessantly pointed out the need for more and better training programs, as well as the need for improvements generally in the University's programs in biological, chemical and radiation safety. When we suggested methods for identifying and monitoring the storage and handling of chemicals, the University's response was: These are excellent ideas, but we don't have the resources. When we pushed for better training for the custodial staff, the response was to set up short sessions which condescendingly refer to radiation as being no more hazardous than Mom's apple pie, accompanied by a slide of an old woman holding a pie! Lack of adequate resources

devoted to health and safety can only result in the lack of an adequate program.

but Locals 34 and 35 should not be placed continually in the position of being the bad guy. Yale University is known for being a campus wracked by labor unrest. In the last twenty years there have been five strikes on campus. The first four involved Local 35 and the last involved both Local 34 and Local 35. All too often the Unions' efforts to deal with issues of health and safety were seen by the administration as a labor relations issue, rather than sincere concern for workers' safety.

We have seen changes in this attitude and welcome them. Until recently, the joint Union-University Health and Safety Committees were chaired by the Managers of Labor Relations. Recent negotiations have resulted in the permanent assignment of the Director of the Department of Occupational and Environmental Health to chair a new combined joint Health and Safety Committee. At last, through negotiating two excellent Union contracts this past January, the University and Yale have hopes of proceeding amicably and in a professional manner.

Locals 34 and 35 have been working to raise the standard of health and safety at Yale University. Government oversight over DOD-sponsored research at Yale would impose only a minimum standard over a very small number of biohazard laboratories. It would be our hope that at some point regulations governing research on biohazards in all labs be imposed. Requiring that the University be accountable to the Government concerning the research performed in two of its 350 biohazard labs is but a small step, but a significant step in the right direction. From the point of view of the 3,600 workers in our bargaining units, any attempt by anyone to beef up Yale's Health and Safety Program would be welcome.

In the early 1970's an incident in YARD resulted in a worker fatality. Perhaps federal oversight might prevent such an occurrence from ever happening again.

Dr. Gregory H. Tignor
Associate Professor of Epidemiology
Yale University School of Medicine

Mr. Chairman and members of the Subcommittee, I am Dr. Gregory H. Tignor. I am thankful for the opportunity to address you this morning on behalf of Yale University and the faculty and staff of the University who are involved in research funded by the Biological Defense Research Program ("BDRP") of the United States Department of Defense. I speak also for myself, a scientist, the deputy director of the Yale Arbovirus Research Unit, a tenured faculty member of the Yale University School of Medicine and Graduate School, and a citizen concerned passionately for the health, welfare and safety of my fellow citizens of this country and the world.

The Yale Arbovirus Research Unit houses research under two contracts funded by the BDRP. This research involves some 16 faculty members and laboratory personnel and represents less than one-percent of the externally funded biomedical research activity of the School of Medicine. Nonetheless, BDRP funding, along with support from the National Institutes of Health and the World Health Organization, has enabled the Arbovirus Research Unit to play a leading role nationally and internationally in building scientific understanding of arboviruses: that is, viruses transmitted by mosquitos, ticks and other biting arthropods.

I will first discuss the origin of Yale's participation in the Biological Defense Research Program. I will then describe for you the biological safety program at Yale as it applies to the BDRP research in which we are engaged.

Investigators at the Yale Arbovirus Research Unit have a long history of concern with tropical diseases, especially those diseases which severely threaten the health of third world nations. The intellectual and humanitarian overlap of our concerns with those of the military historically go back to the work on yellow fever by both General Walter Reed and the late Nobel prize winner Professor Max Theiler, the developer of yellow fever vaccine, the first director of the Arbovirus Research Unit, and, I am proud to say, a colleague of mine.

Our current work with viruses in the BDRP is a continuation of our earlier work with the same agents which was — and is still being — supported by the National Institutes of Health. We are nationally recognized for our long research involvement and experience with these viruses as causes of tropical disease. We conduct research in the development and testing of diagnostic reagents and antiviral drugs under the BDRP because the viruses we study pose health threats not only to tropical nations but also to U.S. travelers to those regions, and indeed to the U.S. mainland itself. These viruses exist in nature; we are adding nothing new to the environment nor would we consider that. Arthropod-borne viruses are capable of being transported from one zoogeographic region to another and this apparently has indeed occurred in the past. These facts demand both international and domestic surveillance.

We believe our research is vitally important to the control of the tropical disease burden borne by nations economically unable to support a research infrastructure. In the last twenty years, thousands of people have

been infected in nature with the viruses under study in this program; reducing that morbidity which consistently inhibits economic development and freedom is the primary research goal of our efforts in testing antiviral drugs. That goal has coincided with the unique interest of the military in the practice of clinical tropical medicine using optimum intervention therapies. Since the current infectious disease mission of the U.S. Public Health Service is largely directed toward urgent domestic disease concerns, research support from the DOD has been important in maintaining research efforts in tropical medicine, an area which might otherwise be neglected.

We entered this program aware of its positive benefits and aware that its inherent hazards would be carefully circumscribed by our safety practices and procedures. Since the establishment over a decade ago of Yale's program for oversight of biological safety, which I will describe to you, there have been no laboratory illnesses and no known laboratory or community infections associated with EDRP research, and there has been only one instance -- not involving EDRP research -- of a laboratory illness in the Arbovirus Research Unit. That illness was followed by complete recovery.

I will now describe briefly the organizational structures, operating procedures and facilities which are used at Yale in general, and in the Arbovirus Research Unit in particular, to ensure that research of this kind is conducted safely.

Laboratory safety at Yale has received substantial increased attention by the University administration over the past two decades. A Biological Safety Advisory Committee has functioned throughout most of that period and a full-time professional Office of Biological Safety was established in 1979. In 1980, that Office produced a manual for biological safety in the laboratory which was distributed to over 300 other institutions, many of which have used it as the model for developing their own safety programs. Yale's biological safety office has also organized a number of national symposia on safety management.

Yale's leadership in the field of biological safety is further exemplified by the fact that Dr. Edward A. Adelberg, the University's Deputy Provost for the Biomedical Sciences, is currently serving as Chairman of the National Academy of Sciences committee that is preparing guidelines for biological safety in the laboratory to serve as a national reference.

At Yale, responsibilities for providing institutional safety oversight of laboratory research rests with departmental safety committees; the Biological Safety Officer, who is Manager of the Department of Biological Safety within the University's Division of Occupational and Environmental Health Services; the University's Biological Safety Advisory Committee; and the Deputy Provost for Biomedical Sciences. Other safety departments within the Division of Occupational and Environmental Health Services include chemical safety, environmental health, occupational safety and radiation safety.

Review takes place through the University Biological Safety Committee, two of whose members are not affiliated with Yale and represent the local community. There is frequent discussion with community leaders, including the Director of the New Haven Health Department, and local fire and police officials. The University's Biological Safety Officer provides, on a continuing basis, services which include regular inspection of facilities, oversight of the annual medical surveillance of personnel, review of equipment certifications, technical consultations related to biological safety measures, and specialized education and training where needed and/or requested. For example, the Biological Safety Officer oversees training and vaccination of maintenance or emergency personnel who may require access to high security areas.

The University's employee health service is equipped to clinically evaluate and to treat any work-related injuries or illnesses which might occur during the course of laboratory research efforts. In addition, employee participation meetings, as mandated by contractual agreements with Yale-based unions, are conducted on a quarterly basis. At these meetings, open to all staff members, various issues including safety concerns are discussed. Employees are able to present agenda items as well as query the Department Chairman and senior administration officials on matters of concern.

With the above individuals, programs, and committees in place, there is a deliberate redundancy of effort in monitoring biological safety. This provides the safety factor necessary for the conduct of a responsible

institutional safety effort. The ongoing level of interaction between employees and supervisors within the University, and among the several components of the institutional safety efforts, assures that safety-related issues quickly come to the attention of those in a position to react in an appropriate manner.

Within the Yale Arbovirus Research Unit itself, safety is achieved through the use of a multi-tiered system of barriers. The primary barrier is concerned with establishing and maintaining the competence of the individual workers handling hazardous virus agents. Toward this end, only qualified, experienced and trained principal investigators can obtain internal approval of grant or contract application by the Department Chairman and the Grants and Contracts Office of the Yale School of Medicine. Principal investigators and all personnel receive health assessments and applicable vaccines before commencing work. The University Biological Safety Committee must approve the protocol before a given research project can be conducted. Animal care protocols must be approved by the University Committee on Animal Care and Use. The principal investigator selects research assistants and support personnel directly involved in carrying out the research-related work and conducts the training specific to the given project. All state and federal regulations are met or exceeded in hiring and training practices. Methodologies, although individualized, are in keeping with standard published procedures and CDC/NIH guidelines as approved by the University Biological Safety Committee. Work does not begin before these criteria are met.

The secondary barrier includes all measures related to isolation and containment of infectious agents. Infectious agents are manipulated only in biologic safety cabinets equipped with high efficiency particulate air ("HEPA") filters. These cabinets are constantly monitored internally and inspected externally on an annual basis. Virus repositories are kept locked with sharply limited access. If infectious virus must be transported from one physical area to another, it is enclosed in double-contained unbreakable vessels. Infected animals are held in high security containment areas. Infectious materials and/or potentially infectious waste materials are rendered non-infectious by chemical treatment, followed by heat-inactivation using high-temperature autoclaves which are systematically maintained and monitored. Following autoclaving in specially marked bags, the inactivated waste materials are double-contained in puncture-proof vessels for transport for incineration.

Tertiary barriers at the Yale Arbovirus Research Unit include all measures related to physical isolation of the entire facility, including workers and viruses, from unauthorized individuals. Laboratories are isolated on specific floors of the Laboratory of Epidemiology and Public Health. Individual rooms possess controlled unidirectional airflow, without recirculation of exhaust air. Access to areas where high-security work is ongoing is limited both by international biohazard warning signs and by locked, double door barriers. One specially designated elevator is used for the transport of infectious materials. Emergency control of liquid waste disposal is provided by liquid waste holding tanks in the building. In the event of a power failure, emergency generators are available.

The proper operation of the three barrier levels is the joint responsibility of the principal investigators and the Unit's Director, with the advice and surveillance of the University's safety offices and committees as described above. In addition, the Yale Arbovirus Research Unit has had the benefit of external advice and review including review by NIH peer review panels as well as by DOD.

In summary, we believe the association of our academic center with the military tropical disease research program builds on a great tradition established by Walter Reed and the late Nobel prize winner, Max Theiler, the first director of this research unit. We believe that wise and systematic application of existing and new technologies and active peer group review will enable research of this sort to advance in an environment made even more secure and safe.

OPENING STATEMENT

OF

EDWARD L. PYLES

The following is my view of the transport, storage and use of a very hazardous agent as seen through the eyes of a fire department officer who has had first response accountability in the event of a mishap. I am not a biologist nor a chemist and have a very limited experience with nerve gas agents.

I would like to begin with a brief history of events as I know them. Early in 1983, the Geomet Technologies, Inc. began its operation in our area. This facility was under contract with the Department of Defense to conduct tests using nerve gas agents. As you probably have guessed by now, this caused a great deal of concern among the citizens in the area as well as local government officials and the fire department.

Our Department has from time to time received notification that shipments of hazardous materials would arrive at the airpark and would be transported to the Geomet Laboratory at 8577 Atlas Drive. The Geomet Laboratory and the Montgomery County Airpark are located in our Department's area of responsibility.

I have observed a delivery to the airpark and to the laboratory to enable us to develop an emergency plan of action. After which I issued an interdepartmental memorandum cautioning our personnel on interior fire and rescue efforts at the Geomet Laboratory. Late in 1984, during a review of our Department Emergency Pre-Plans, I advised Technician Mark Bird to reissue a memorandum to reenforce our previous position.

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On June 13, 1985, Assistant Fire Marshall, Theodore Jarboe, and I toured the Geomet facility and at that time made some recommendations for safety improvements which were complied with.

I would like to address my concerns about the transport and the use of nerve gas agents in the testing laboratory.

First, the Air Force, Army nor Department of Defense, being the notifying agent, provided to our Department little or no information on the emergency handling procedures of these agents except to inform us that a delivery was taking place. I understand that a meeting was scheduled in late 1983 which was to be attended by the Army, but they did fail to attend. It is also my understanding that there is no requirement of law that would cause the Department of Defense to supply information or training to local government agencies. My experience in observing one particular delivery is that there was very little coordination nor instruction on handling an emergency involving these agents. This shipment I observed arrived late with no information as to a new estimated time of arrival. I also questioned the Montgomery County Police officer at the scene as to their procedure and was informed that there was no plans of alternate routes or plan of action in case an accident were to occur but I was advised that they were there to assist us and the Army. Information our Department was receiving was somewhat limited sometimes heresay and at times second and third hand. This is why I feel there is a need for direct official contact and training. This should be provided by the Department of Defense to the local fire departments

- 3 -

who has first response accountability for controlling the emergency whether it be in the laboratory or on the highway.

Second, Geomet Technologies, Inc. has been very cooperative and professional with our Department in supplying information and some insight into the handling of an emergency at their laboratory. I must confess that they were not unable to view the situation as through our eyes. Congress has, by passing Public Law 99-499, or SARA Title III, taken what I see as a major step in the identifying the presence of certain hazardous materials in local communities, but this law does not cover testing laboratories using small quantities of extremely hazardous, dangerous and deadly agents. By my calculation these regulations would not have covered Geomet Laboratories, but in their own Safety Manual they describe the testing as extremely toxic with hazards unfamiliar to the average chemist. The Montgomery County Council Draft Task Force Report of 1986, recommends the introduction of legislation to control such laboratories. I believe that at this time the legality of such a local law is being investigated.

I would like to summarize by making the following points:

- (1) I feel that the location of even the small quantities of these extremely toxic agents must be disclosed.
- (2) Guidelines as to where these laboratories should be located must be considered.
- (3) Local emergency response units must know the route of travel, time of transport and have some input into both.

- 4 -

- (4) Training in the control of accidents whether they be from little foresight, poor or inadequate safety practices, carelessness or malice must be provided to the local fire/rescue departments accountable for control of the accident.
- (5) I encourage you to use the Montgomery County Council Draft Report as a guideline document.

REFERENCES:

Implementation Guide Title III SARA PL 99-499.

SARA Title III Consolidated Chemical List.

Geomet Technologies, Inc. Safety Manual.

Use of Toxic and Hazardous Substances, Montgomery County Council Draft Report.

STATEMENT OF JEREMY RIFKIN

PRESIDENT OF THE FOUNDATION ON ECONOMIC TRENDS

I. INTRODUCTION

I am Jeremy Rifkin, President of the Foundation on Economic Trends (Foundation). The Foundation is a public interest organization which assesses the economic, environmental and ethical risks involved in emerging technologies. Over the past several years a major focus of the Foundation has been the regulation of developments in biotechnology. A particular concern of the Foundation has been the use of biotechnology and genetic engineering in biological warfare research.

The Foundation on Economic Trends has in the past engaged in actions which temporarily halted certain biological warfare research work. We have focused public attention on the military application of genetic engineering technology, and we have forced the Department of Defense (DOD) to prepare environmental impact statements (EISs) on the health and environmental implications of the biological defense research program (BDRP).

In December, 1984, the Foundation and other plaintiffs filed a motion for preliminary injunction to enjoin the construction of the proposed aerosol biological warfare testing facility (BATF) at Dugway, Utah. We maintained that the Army had not prepared an environmental assessment (EA) for the facility and was therefore not in compliance with the National Environmental Policy Act (NEPA). Approximately one month later, the Army released an EA for the BATF. Contending that the EA was grossly inadequate, we quickly moved for a permanent injunction on the facility.

On May 31, 1985, Federal District Court Judge Joyce Hens Green permanently enjoined the construction of the lab citing the "serious and far-reaching risks" involved in its operation. Judge Green held that the EA was "clearly inadequate" and a "substantive violation" of NEPA. She concluded that "[g]iven the deadly nature of the material being tested, considerations of the larger interests of society--particularly concerns for public health and safety--militate heavily in favor of enjoining construction." See Foundation on Economic Trends et al. v. Caspar W. Weinberger et al., 610 F. Supp. 829 (D.D.C. 1985). The Department of Defense released the BATF draft EIS in January of 1988. The Foundation has submitted comments on the draft EIS, outlining its substantial procedural and substantive inadequacies.

In September of 1986, the Foundation filed another law suit against the DOD calling for a programmatic environmental impact statement (EIS) on the entire Biological Defense Research Program. On February 17, 1987, the U.S. District Court of the District of Columbia ruled for the Foundation and ordered that the DOD undertake the preparation of a programmatic (EIS)

covering all 129 private and military laboratories which conduct biological warfare research. On August 12, 1987, the Foundation participated in the "scoping" of this EIS. We insisted that its major concerns about the efficacy of the biological warfare program, its security, and its environmental effects be included in the court ordered environmental documentation. The Army released a draft of the BDRP EIS in May 1988. The Foundation submitted comments on this EIS and once again found the EIS wholly inadequate in assessing the environmental hazards of the BDRP.

II. ENVIRONMENTAL AND HEALTH IMPACTS OF THE BDRP

The BDRP is devoted to research in "militarily significant" bacteria, viruses and toxins. These pathogens can be used to destroy animals, crops, and people. Biological agents can mutate, reproduce, multiply and spread over a large geographic areas by wind, animal, and insect transmission. Once released, many biological pathogens are capable of developing a viable niche and maintaining themselves in the environment indefinitely. Traditional biological agents include yersinia pestis (the plague), anthrax, botulism, snake venom, tularemia, rift valley fever, coxiella burnetii (Q fever), eastern equine encephalitis, and small pox. These pathogens are selected for research because they have potential use as warfare agents due to, inter alia, their pathogenicity, quick infectivity, and ability to rapidly disseminate.

Moreover, the BDRP is involved in large scale genetic engineering of biological warfare agents. In a May 1986 report to the Committee on Appropriations of the United States House of Representatives, the Department of Defense pointed out that recombinant DNA and other genetic engineering technologies are finally making biological warfare an effective military option. Genetic engineers are cloning previously unattainable quantities of "traditional" pathogens. The DOD report states that: potent toxins which until now were available only in minute quantities, and only upon isolation from immense amounts of biological materials, can now be prepared in industrial quantities after a relatively short developmental period. This process consists of identifying genes, encoding for the desired molecule and transferring the sequence to a receptive micro-organism which then becomes capable of producing the substance. The recombinant organisms may then be cultured and grown at any desired scale...Large quantities of compounds, previously available only in minute amounts, thus become available at relatively low costs. 1

Using recombinant DNA technology, it is now possible to develop a nearly infinite variety of "novel" designer biological

warfare pathogens never before seen. The DOD report summarizes:

[new advances in biotechnology]...permit the elaboration of a wide variety of 'novel' warfare materials...The novel agents represent the newly found ability to modify, improve or produce large amounts of natural materials or organisms previously considered to be militarily insignificant due to problems such as availability, stability, infectivity and producibility. 2

Recombinant DNA "designer" weapons can be created in many ways. The new technologies can be used to program genes into infectious micro-organisms to increase their antibiotic resistance, virulence, and environmental stability. It is also possible to insert lethal genes into harmless microorganisms resulting in biological agents that the body recognizes as friendly and does not resist. It is even possible to insert genes into organisms which affect regulatory functions that control mood and behavior, mental status, body temperature, and other functions. Scientists say they may be able to clone selective toxins to eliminate specific racial or ethnic groups whose genotypical make-up predisposes them to certain disease patterns. Genetic engineering can also be used to destroy specific strains of agricultural plants or domestic animals if the intent is to cripple the economy of a country. In recent months advances have been made in the creation of genetically engineered microbes which are designed to self destruct after a given period of time. In sum, the implications of this, and other advances in genetic engineering, are extraordinary and frightening.

Due in part to genetic engineering the BDRP has expanded 500% over the last 6 years. In 1981, the Pentagon budget for "defensive" biological warfare research was only \$15.1 million. In fiscal 1982 it rose to \$21.6 million. In fiscal 1983 it jumped again to \$38.8 million. In 1984 it rose still higher to \$39.1 million. In 1985 the DOD budget grew to \$50 million and in 1986 to \$90 million. The 1987 expenditures are estimated to be close to \$70 million. 3

The BDRP has the potential for significant adverse effects on the environment and public health. According to the DOD, biological warfare research is ongoing in more than 19 government labs, 50 non-governmental research labs and institutions, and over 85 colleges and universities.4 As noted, this research involves numerous bacteria strains such as Salmonella marcescenes, and Yersinia pestis, numerous viruses including Rift Valley Fever, Yellow Fever, poliovirus, Ebola and Marburg viruses and human retroviruses; and more than seventy toxins, including T2 mycotoxin, Scorpion toxin, and Mojave rattlesnake toxin. The BDP has also conducted over 75 recombinant DNA experiments. 5

The environmental concerns about this research include 1) effects on the general public from potential exposure to biological warfare agents during normal operations or due to advertent or inadvertent release of the hazardous organisms (i.e. human error, equipment failure, terrorism, or natural disasters); 2) effects on DOD personnel from potential exposure to biological warfare agents being researched; 3) impacts on the thousands of national and international volunteers being used in BDRP projects; 4) impacts on air, and water quality and biota from BDP operations or accidents; 5) laboratory security; 6) risks involved in decontaminating facilities; 7) treatment and disposal of BDP research wastes; 8) economic and social impacts to areas adjoining BDP sites, and 9) transportation and shipping of BDP pathogens.

The BDRP has never instituted a comprehensive study on accidental exposures and other hazards of the BDRP. The DOD has admitted that there have been approximately 20 "potential accidental exposures" at Fort Dietrick since 1983, but the DOD has not provided information on the rest of the BDRP.⁶ There have also been widely reported cases of fires and other accidents at Fort Detrick including missing quantities of viruses. One of the most recent incidents is the loss of a sample of Crimean Congo hemorrhagic fever en route from the Center for Disease Control to the BDRP lab at Fort Detrick, Md. According to the National Institutes of Allergy and Infectious Diseases the Congo fever virus is so "highly infectious" that "most labs won't work on it."⁷ With this virus, and many others being worked on in the BDRP labs even small amounts of the pathogen if dropped from a plane or truck or dumped into the water supply, could have devastating effects.

Additionally, the danger of experimentation with pathogens is highlighted by the reporting of several NIH research experiments, not related to the BDRP, which have led to the infection of workers with the pathogens ranging from pertussis to AIDS. One internal NIH report on such accidents pointed to the need for upgraded standards when dealing with large scale research activities with pathogens because of, *inter alia*, "the potential for introducing infective agents into the community outside the laboratory."⁸

The dangers of BDRP research have been noted by many in Congress and the public health sector. Senator Orrin Hatch (R-UT) has maintained that BDRP research in populated areas constitutes "reckless endangerment" and has advocated "a remote island for any future biotoxin work."⁹ Dr. Anthony Robbins past President of the American Public Health Association has summarized, "[w]eapons designed and built with modern biotechnology will leave us no reasonable opportunity to protect

the public. This is true whether the public is exposed by military attack; by accident; or by terrorism. Advances in genetic engineering and other new techniques of biotechnology have magnified both the theoretical lethal capabilities of biological agents, and their potential to create public health catastrophes."¹⁰

The recently released Department of Defense Annual Report on the BDRP (October 1986 through September 1987) demonstrates that the BDRP is expanding in many important areas. The Annual Report demonstrates that the BDRP is continuing to aggressively investigate, purify, propagate, clone and alter traditional and new pathogens. The BDRP is also expanding its vaccine program to include large numbers of national and international volunteers. The 1987 Annual Report states that the BDRP has "established protocols for field testing efficacy of Argentine hemorrhagic fever vaccine in 3,000 volunteers residing in endemic disease areas."¹¹ The increase in the number and type of pathogens being investigated by the BDRP and the expanded use of international volunteers in BDRP programs causes a growing potential for health and safety risks. The expansion of the international research in the BDRP comes at a time when the NIH is still undecided as to how its research Guidelines apply to research done abroad.

Even as the BDRP expands, an internal Army Science Board report evaluating the BDRP (July 1987) states that "there is a serious lack of clear-cut assignment of responsibility together with authority to control the program's direction and outputs." The report concludes that "there does not presently exist within the Army an adequate mechanism for assuring the systems integration of the total BD program."¹²

This lack of integration and coordination is particularly evident in the DOD's apparent inability to assess and minimize the environmental and health impacts of the BDRP. The DOD is content to allow the BDRP's impacts to be governed and monitored by a series of regulations, the enforcement of which is the responsibility of numerous agencies. These include the Department of Transportation (Packaging standards, 49 C.F.R. sec. 173), Environmental Protection Agency (Toxic Substances Control Act, 5 U.S.C. secs. 2601-2929; Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. secs. 136-136y), US Department of Agriculture Virus-Serum-Toxin Act: 21 U.S.C. secs. 151-158), Food and Drug Administration (Food, Drug and Cosmetic Act: 21 U.S.C. secs. 301 et seq.) and the Nuclear Regulatory Commission (use of radioactive isotopes, 10 C.F.R. sec. 1). In addition, DOD voluntarily follows the NIH guidelines governing recombinant DNA (rDNA) work (49 Fed. Reg. 40659 (1984)).

It is clearly not sufficient for DOD to rely on the present regulatory tangle to insure that the public and the environment

are protected from the potential impacts of the BDRP.

III. RECOMMENDATIONS

The Army Science Board (ASB) evaluation of the BDRP resulted in several recommendations. These include the setting up of a "red team" under the U.S. Army Training and Doctrine Command (TRADOC). The "red team" would include biological scientists with "appropriate training" who would be responsible for creating realistic threat scenarios in the BW area. These scenarios are to include BW use in various combat situations and in terrorism. These threat scenarios would then be used as a basis for increased appropriations and priority for the BDRP. The ASB believes that the red team scenarios could be essential in reversing a pattern of insufficient priority and resources allocated to the BDRP. The ASB report also recommends increased research on how an opponent might "enhance or greatly alter the pathogenicity, survival, capacity, dissemination potential, susceptibility to detection, and identification of viable BW agents." The ASB recommends the expanded use of genetic engineering research for this purpose. Finally, aware that this expansion of the BDRP will be controversial, the ASB recommends an aggressive public relations campaign, including dissemination of the red team's threat scenarios to the public. An appendix to the report also suggests ways of handling critics of the BDRP, myself specifically included. 13

We believe that the ASB suggestions are dangerous and lead to the very real possibility of an expanded genetic arms race. These suggestions could lead to an increase in environmental and safety hazards; they are not the way to minimize the adverse impacts of the BDRP. Rather than an expansion of the BDRP, including increased genetic engineering and an aggressive PR campaign, the way to minimize the environmental impacts of the BDRP is to significantly modify its implementation. This alteration would have to involve change in the conduct, type and scale of BDP activities.

The first step in improving the conduct of BDRP activities would be to shift the recombinant research currently ongoing at the BDRP to civilian agencies. The DOD should declare a moratorium on the use of recombinant DNA research and shift research which has public value to the civilian agencies such as the NIH or CDC. Other changes should include the establishment of an independent review committee to assess the environmental and health implications of BDRP research. Additionally, there should be mandatory reporting of all BDRP accidents with full investigation of any such accident. Moreover, the BDRP should make available to the public an updated list of all pathogens being researched, the location of such research, and the safety and security measures, including emergency protocols, for all

such locations. All new and/or controversial research should be published in the federal register for full notice and comment. Finally, changes in BDP activities should include a total commitment to the use of simulants rather than the toxic materials currently in use.

An important change in the scale of the BDRP would be the requirement that all BDRP researchers and research location keep a careful inventory of all BDRP pathogens. Additionally, no new pathogens should be investigated by the BDRP unless there is some intelligence that there is a real need for defensive research into such pathogens.

Finally, the environmental impacts of the BDRP program could be minimized through a change in the location of BDRP operations. Such research should not be dispersed through the several dozen laboratories currently in use. Instead any BDRP research found absolutely necessary should be located at remote sites away from populations. Environmental and safety consideration should, and legally must, be included in the decision as to which facilities will conduct which parts of the BDRP.

FOOTNOTES

1. Department of Defense Biological Defense Program, Report to the Committee on Appropriations House Representatives, May 1986, p. 4.
2. Ibid., p. 8.
3. Department of Defense, Annual Report on Chemical Warfare - Biological Defense Research Program Obligations, 1 October 1986 through 30 September 1987. p.1.
4. See list of laboratories involved in BDRP research in Draft Programmatic Environmental Impact Statement, Biological Research Defense Program, May 1988, Appendix 3.
5. See partial list of BDRP pathogens Answer to Plaintiff's Interrogatory No. 4, Foundation on Economic Trends et al v. Weinberger et al., Civil Action No. 86-2436.
6. See Programmatic Environmental Impact Statement, Biological Research Program, Appendix 8..
7. Associated Press Wire Report, The News, Frederick, M.D., Saturday May 30, 1987, A-5.

8. NIH Draft Report "Laboratory Acquired Pertussis Associated With Pilot Plant Production," (11/20/86), p.5.

9.. "Hatch Proposes Island Location for Germ Warfare Testing," Press Release, Office of Sen. Hatch, March 25, 1988.

10. Statement of Anthony Robbins M.D. to the Committee on Interior and Insular Affairs, Subcommittee on Energy and the Environment; Committee on Foreign Affairs Subcommittee on Arms Control; International Security and Science Committee on Armed Services, Subcommittee on Military Installations and Facilities, May 3, 1988.

11. p. 61.

12. Department of the Army, Army Science Board, "Final Report of the Ad Hoc Subgroup on Army Biological Defense Research Program," July 1987. p. 5.

13. Ibid. p.9; Appendix 3.

STATEMENT BY

DR. THOMAS J. WELCH

DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE

(ATOMIC ENERGY) (CHEMICAL MATTERS)

Good morning. I am Dr. Thomas Welch, Deputy Assistant to the Secretary of Defense for Chemical Matters. I am pleased to be here this morning to testify regarding the safety of DoD funded research, development, testing and evaluation programs related to chemical warfare and chemical/biological defense.

At the outset, I would like to emphasize the Department of Defense does not conduct any research and development related to offensive biological warfare; we have no biological warfare capabilities or programs. We are in strict compliance with the Biological and Toxin Weapon Convention and US national policy. Our biological defense research program is conducted solely to enhance our ability to protect and defend the men and women of our armed services from the very real and worldwide threat of biological warfare. In that regard, I would like to again encourage the members of Congress to receive a classified biological warfare threat briefing presented by the Defense Intelligence Agency.

I intend to divide my remarks into two parts--chemical warfare and chemical defense followed by biological defense.

Chemical Warfare and Chemical Defense Research Programs

There are potential safety risks to research personnel, the workplace and to the environment associated with conducting

the chemical research programs. To ensure safety of these DoD funded programs, both in-house and contract, we have systems in place which effectively combine risk analyses, evaluations and inspections to minimize these risks.

The Army, as the responsible DoD Agency, applies stringent safety, storage, maintenance, use and accounting requirements for all internal and contractor facilities that use chemical agents. These are elaborated in Army regulation 50-6. Facilities, equipment and procedures are subject to continuous formal and informal inspection and review--both announced and unannounced--and to rehearsal of actions taken in response to hypothetical accidents. These inspections and reviews serve to assure that the combined facility, equipment and procedures are effective. In response to a study of Army chemical safety programs by the Department of the Army Inspector General, the Army Safety Office is drafting a comprehensive Army regulation on chemical safety. The Director of Army Safety and Commanders of Army research organizations have been directed to enhance their oversight and management of chemical safety programs.

It is appropriate to emphasize that the DoD's stringent and necessary safety precautions for chemical operations supplement other applicable federal, state and local safety requirements. While the focus of the Department's chemical safety programs has been on insuring compliance with DoD requirements, institutional safety offices are responsible for

assuring that these other applicable safety requirements are also met.

Finally, our system of continuous review of the adequacy of our regulations and management practices has resulted in constant improvement of our process.

In response to your question concerning regular safety inspections of chemical research facilities by agencies outside of DoD, we believe that a more practical approach would be for the Department to consult with other qualified Federal agencies. The Department would modify existing safeguards/controls where necessary to accommodate agreed upon recommendations. DoD would continue to inspect safety of Army and other Services and contractor activities using the agreed upon safety inspection procedures. This approach is consistent with that used in other DoD programs and avoids statutory and regulatory conflicts within these essential national defense programs.

Biological Defense Research Program

The risks and safety precautions of the Biological Defense Research Program have been extensively addressed in the Draft Programmatic Environmental Impact Statement, Biological Defense Research Program, May 1988, and at public hearings. Handling

of highly infectious, pathogenic or exotic organisms and toxins poses a potential risk to laboratory personnel, the workplace and the environment. Thus biosafety facilities, specialized procedures and safety equipment, as well as occupational health programs, have been developed to minimize these risks. Like all DoD funded research, the biological defense research program must comply with applicable Federal, state and local laws and regulations. This Subcommittee's Preliminary Report, 11 May 1988, identified that DoD expects, but does not require, adherence to the CDC-NIH Guidelines, "Biosafety in Microbiological Laboratories". Responding to that report, DoD directed that all aspects of the Biological Defense Research program --both in-house and contract--comply with these CDC-NIH Guidelines. In addition, senior Army leadership directed that the Army Safety Office develop an Army Regulation on Biological Defense Research Safety. This regulation is being drafted at this time.

While the Department would not oppose regular safety inspection of DoD sponsored biological defense research facilities by another qualified Federal Agency, in addition to those which already have access to our facilities, the merit of such inspections is not readily apparent.

It must be recognized that the facilities, special safety equipment and practices which are contained in the Center for

Disease Control-National Institutes of Health Guidelines, "Biosafety in Microbiological Laboratories", evolved from those developed by the Army, the National Institutes of Health and the Center for Disease Control. These organizations continue to work together to enhance the safety of biological defense research. To have the most credible non-DoD activity, the Center for Disease Control, inspect Army facilities would place an unnecessary regulatory oversight burden upon the Center for Disease Control.

In conclusion, the Department will continue to be uncompromising in maintaining safety and security standards in chemical warfare and chemical/biological defense research programs. We recognize our responsibility to keep Congress and the American public informed, especially of those programs that involve the safety of American citizens and the environment.

Thank you. The following personnel are present to assist in answering your questions where possible:

Brigadier General Peter Hidalgo, Commander, US Army
Chemical Research, Development and Engineering Center, Aberdeen
Proving Ground, Maryland.

Mr. Thomas Dashiell, Director, Environmental and Life
Sciences, Office of the Secretary of Defense.

Colonel Marvin Mitchiner, Director for Army Safety,
Headquarters, Department of the Army.

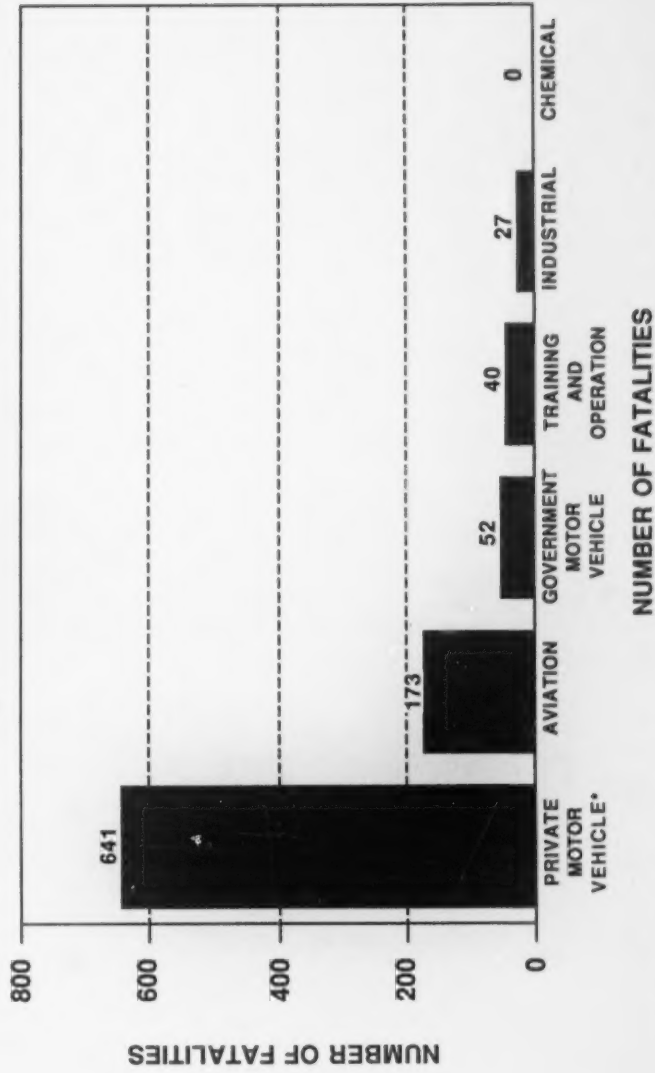
Colonel David Huxsoll, Commander, US Army Medical Research
Institute for Infectious Diseases, Fort Detrick, Frederick,
Maryland.

Colonel Michael Reardon, Director, Medical Chemical
Defense Research Program, US Army Medical Research and
Development Center, Fort Detrick, Frederick, Maryland.

DoD ON/OFF DUTY FATALITIES

FY 87

TOTAL FATALITIES = 933

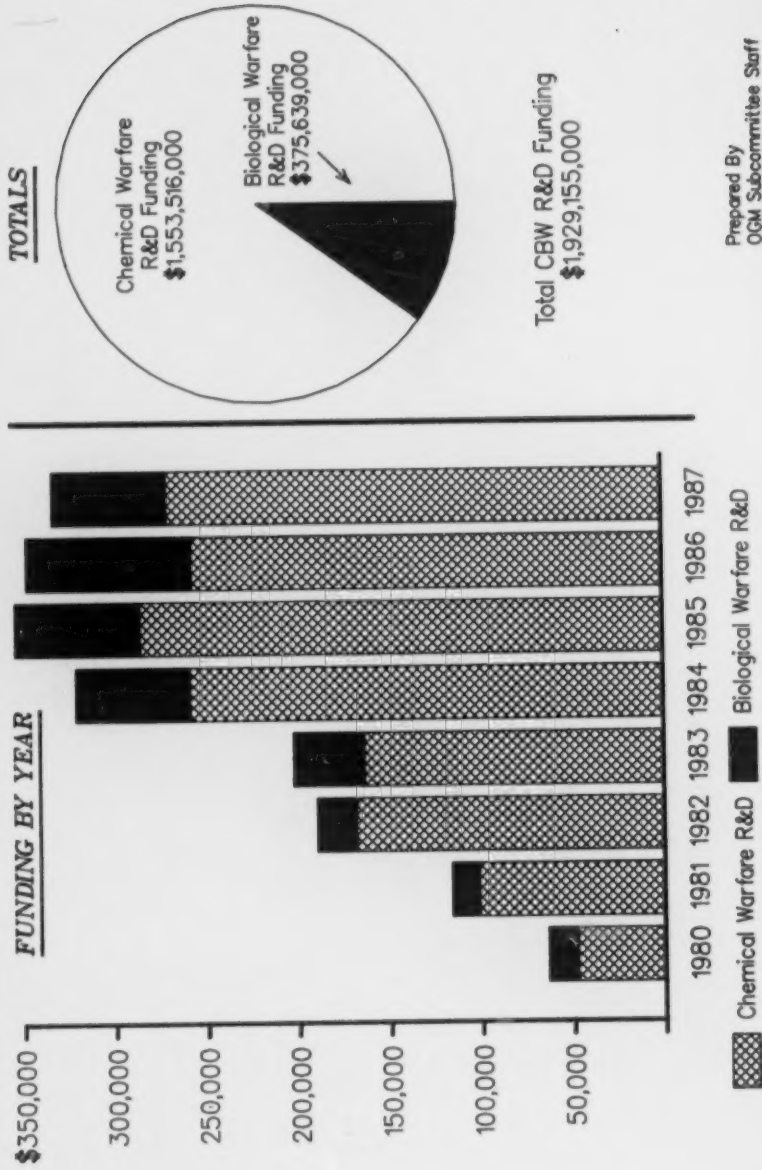


* OFF DUTY DoD CIVILIANS NOT INCLUDED.

8-5000

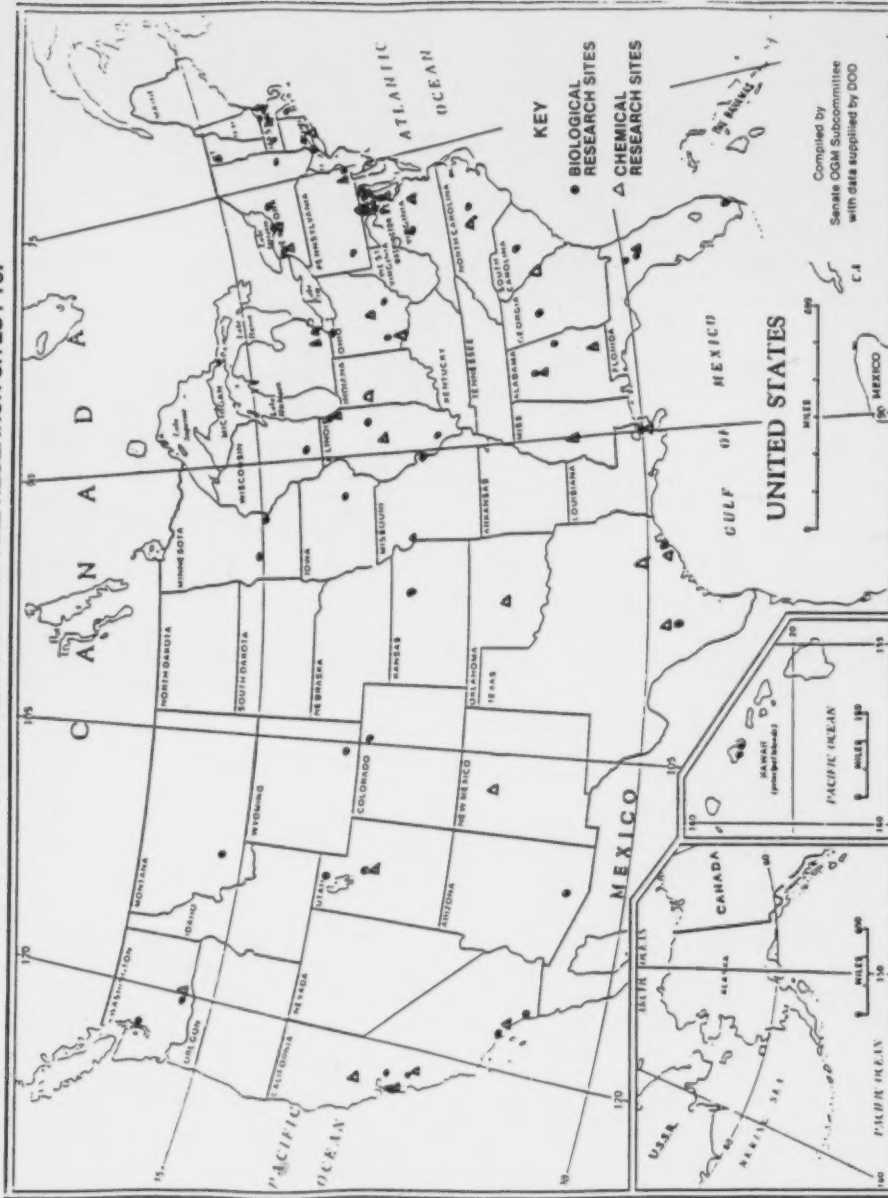
CHARTS

FEDERAL FUNDING OF
CHEMICAL AND BIOLOGICAL WARFARE RESEARCH, 1980-1987



Prepared By
OGM Subcommittee Staff

BIOLOGICAL and CHEMICAL WARFARE RESEARCH SITES FY87



EXHIBITS

MINUTES - BIOLOGICAL SAFETY ADVISORY COMMITTEE

This meeting was held on Thursday 19 May in Room 263 JWG at 2:00 PM.

Present: E. Adelberg (Chairman), P. Bhatt, J. Federico, R. Garshon, D. Robinson,
A. Ross, D. Rupp, L. Smith, D. Winograd.

I. MinutesII. Chairman's ReportIII. Recombinant DNA Registration

IV.

V. Biological Safety Officer's Report

The laboratories of 21 PIs in LEPH were inspected and found satisfactory, with only one potentially serious procedural infraction observed (and, presumably since corrected).

Sample of censored minutes provided by Yale University,
referred to by Senator Levin

ADDITIONAL COMMENTS TO MEMORANDUM FOR RECORD. SUBJECT: "UNTOWARD OCCURRENCES IN BIO DEVELOPMENT SUITE 1", DATED 30 DECEMBER 1981 WHICH READS AS FOLLOWS: PARAGRAPH d. "The most significant and disturbing occurrence was discovered by Dr. Levitt on 16 September 1981 while taking a freezer inventory (Calumet SN69483). It was noted at this time that all of the Chikungunya vaccine and production seed was not in the freezer in which it was originally placed. Neither could it be found in any of the other freezers in the Suite. COL Eddy was immediately notified of the missing vaccine. He came directly to the Suite and examined the freezer with Dr. Levitt. LTC Peters was subsequently informed of 2352 ml of missing vaccine, production seed and control fluids. During a subsequent conversation with Mr. Hasty, he remarked that he had noticed space in this freezer two weeks prior to the discovery."

On 16 September 1981, Dr. Levitt was asked by someone (I don't remember by whom at this point in time) if he/she could have some of our CHIK production seed or vaccine to experiment with. A large volume of material was needed and we had 2352 ml of CHIK production seed plus vaccine which we had no use for since neither passed the suckling mouse safety test. This material was of no further use to us, and we had no other alternative but to proceed with the development of a new CHIK production seed and vaccine. At the time that Dr. Levitt found that the CHIK material was no longer in the freezer in which it was placed, I mentioned to him that I seemed to remember that we placed representative samples in another freezer and autoclaved out the bulk samples. He replied that we had not disposed of the bulk samples and that they must have been stolen. I figured that I remembered incorrectly and that he remembered correctly. (Three months had elapsed since the notebook record shows that we had a need to go into that particular freezer for samples, and events that transpire in the course of performing duties in a laboratory can become hazy over a period of time.) If by chance, the CHIK material in question was autoclaved out to permit safe disposal of useless material--and not stolen--no record of this was made in the notebook as it should have been.

Helen H. Ramsburg 14 Jan'

HELEN H. RAMSBURG

"Addendum" referred to in testimony of Col. Huxsoll

FIRE REPORT				REPORTS CONTROL SYMBOLS (RQC-1/AS)	
1. STATION Fort Detrick		2. DATE OF FIRE 23 July 81 0720		3. SEVERE LOCATION OF FIRE Bldg. 753, Bldg 1425, Phase II	
4. DISCOVERED BY Laboratory Technician		5. METHOD OF NOTIFICATION Telephone - Fire Phone 7333		6. DATE AND TIME FIRE OUT 23 July 81, undetermined	
7. BUILDING NO. 1425	8. NAME OF BUILDING Laboratory and Administration	9. NUMBER OF STORIES 2-A	10. DOWNGRESSING (Foot) 398* 359	11. CONSTRUCTION (Type of materials) (a) WOOD (b) PLASTER (c) BRICK (d) OTHER	12. CASUALTIES (Number) (a) KILLED (b) SEVERE (c) OTHER
13. OCCUPANCY Lab./Admin.		14. DESCRIPTION OF DAMAGE TO-- (a) BUILDING item #14 attached		15. OTHER PROPERTY DAMAGED None	
16. AUTOMATIC SPRINKLERS None		17. NAME OF HEAD None		18. SYSTEM (Check) YES NO	
19. AUTOMATIC FIRE ALARM Manual Break Stations only; no Automatic Detection, Central Sta. System		20. NUMBER OF HEADS OPERATED YES NO		21. OPERATION (Check one) ☐ SATISFACTORY ☐ UNSATISFACTORY	
22. NAME AND TYPE OF SYSTEM Manual Break Stations only; no Automatic Detection, Central Sta. System		23. ALARM (Check) (a) CONNECTED TO FIRE DEPARTMENT (b) LOCAL YES YES		24. PROTECTION SYSTEM (a) OPERATION (Check one) ☐ SATISFACTORY N/A ☐ UNSATISFACTORY	
25. EQUIPMENT USED TO EXTINGUISH FIRE None		26. FIRE STREAMS (Number, size, length of hose lines, and diameter of nozzle) None		27. FIRE EXTINGUISHERS (Number, type, and size) None	
28. MOTORIZED FIRE APPARATUS RESPONSE (a) NUMBER (b) CLASS (c) UNIT IDENTIFICATION NO. Admin. Use Vehicle - No Pumper Responded		29. FIRE DEPT. PERSONNEL RESPONSE (a) NUMBER PERSONNEL (b) NUMBER VEHICLES 2 0		30. FACTORS CONTRIBUTING TO EXTENT OF DAMAGE Refrigerant gas ignited in a freezer Open Doors throughout Lab.	
31. PREVIOUS INSPECTION (a) DATE (b) BY 6/11/81 Fire Dept		32. DESCRIBE OCCURRENCE (Use additional sheets, if necessary)			
33. AMOUNT OF LOSS (a) BUILDING (b) CONTENTS (c) OTHER (d) TOTAL 7,998 5,890 0 13,888		34. REPAIRS (a) BUILDING (b) CONTENTS (c) OTHER (d) TOTAL None		35. REVIEWED BY (Signature) (Date)	
36. APPROVED BY (Signature) (Date)		37. APPROVED BY (Signature) (Date)			

DA FORM 3985
1 DEC 73

REPLACES DA FORM 3-2, 1 OCT 54, WHICH WILL BE USED.

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Item #11 Dimensions

Width is 398' for both sections of Bldg. 1425.
Length is 439' for Phase I and 359' for Phase II.

Item #12 Construction

- a. Walls - exterior - 4" brick veneer, 2" airspace, 4" concrete masonry unit.
- interior - 6" concrete masonry unit, epoxy glazed.
- b. Floor - 6" reinforced concrete; dense concrete topping.
- c. Roof - 1 1/4" steel deck, 2" rigid insulation, Built-up roof.
- d. Interior Finish - Epoxy glass on concrete masonry unit walls.

Item #14 Damage

a. Bldg. - Although no structural damage occurred, extensive damage from heat and smoke occurred in Rm. 753. Heat was sufficient to blister the epoxy coating on walls, relieve lead anchors in the ceiling that held electrical conduit and ultra-violet light fixtures in place, melt numerous plastic containers and consume the plexiglass water tanks in use on a lab. bench. Smoke resulting from various synthetics that were either on fire or smoldering, carried throughout the H.V.A.C. duct system and all adjacent rooms and corridor. (see attached incl #4).

b. Contents - One Freezer that caused the fire will require repair/replacement of the third stage compressor and all associated wiring. A second freezer that was exposed to the heat is damaged beyond repair and will be replaced. Two water tanks that were constructed in USAMRIID's shop were consumed and each of two recirculating systems used to control the water temperature in the tanks was damaged. Smoke or heat damage to other contents includes numerous synthetic containers used in the water tanks, chemicals stored in a wall-mounted cabinet above the fire area, one desk and several chairs, various laboratory supplies, glassware, synthetics and materials used in the laboratory suite. (see attached incl #4).

Item # 25 through 27 - No hose streams or Fire extinguishers were used because the fire occurred sometime prior to 0430 hrs., which was the time of the freezer alarm indicating elevated freezer temperature, and was actually discovered at approximately 0652 hrs., when a Lab. Tech. entered the suite. The fire consumed combustibles in the immediate vicinity and self-extinguished due to lack of other combustibles and steam generation from the contents of the water tanks. After being notified by telephone @ 0720 hrs., Acting Fire Station Chief, Clarence Rogers and Firefighter Donald Miltier responded in the Fire Dept. utility van to investigate.

Item 29. Cause - An electrical failure at a 208v. terminal connector on a low temperature freezer compressor caused escaping flammable refrigerant gas to ignite. The low-temp freezer, Calumet Scientific mod. no. F75C-100, ser. no. 69481, contains 3 compressors that operate on a cascade principal with the third stage compressor achieving the lowest temperatures of -60 to 70°C. The refrigerant used in the third stage compressor is a mixture of 5 oz. of Ethane & 1.5 to 2.0 oz of Pentane. Both are highly flammable; Ethane gas boils at -128°F and has flammable limits of -3 to 12% by volume, Pentane Liquid flashes at -40°F, boils at 97°F and has flammable limits of 1.5 to 8% by volume. The refrigerant is used because of it's ability to achieve low temps. in super cold-type freezers. However, it's use in this compressor, Copeland Corp. mod. no. JFPL-0500-IAV, is not recommended. Copeland warrants the compressor for use with R-12 & R-502 refrigerants which are non-flammable. The use of the Ethane-Pentane mixture is the result of the Freezer corporations designing units that will achieve low temps of -70 to -100°C by using the mixture in Copeland's compressor. This mixture coupled with an electrical fault at a glass-type seal at the 208v. connection causes fires when the seal fails due to heat and the escaping gas is ignited by electrical arcing or by high

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heat at the connection. An identical fire of this type occurred in an NCI Bldg. on this installation in March 1981. A copy of the incident report is attached at encl 2.

Item 30 - Factors Contributing to Extent of Damage:

a. Location of Freezer - The freezer was located such that the ventilated end, where the compressors are located, was within 3 to 4 ft. of combustible insulation used on two water tanks in use on a lab. bench. When the escaping refrigerant gas ignited, the styrofoam insulation on these tanks was in direct line with the fire and was readily ignited.

b. Open Doors throughout the Lab. suite - doors in the lab. room were open to adjacent labs and to the corridor. Consequently, smoke damage resulted throughout the lab. suite.

Item 32 - Occurrence

a. At 0430 hrs. 23 July 81, Earl D. Smith, E-1, one of two Surveillance Technicians on duty in Bldg. 1425 received an alarm on a Master Panel in the Engineering Office of elevated temperature in a freezer in Lab. Room 753. According to procedures, Lab. Technician Sherman Hasty was notified at his home since he works in the Bio. Dev. Suite and is knowledgeable of the freezer use. Mr. Hasty saw no need for immediate action because the freezer alarms at temperatures within the range of 15°C above the sub-freezing temperature of 60-70°C. Consequently, the contents remain stable for several hours if the freezer remains closed. However, when Mr. Hasty arrived at Bldg. 1425 and entered the laboratory he realized a fire had occurred and apparently had self-extinguished. At 0652 hrs. Mr. Hasty notified Sp 4 Helen Forrester, the second surveillance tech. on duty, who called Mr. Roy Culler, Bldg. Eng. 1425 at his home. Mr. Culler called the Surveillance Techs by radio, while enroute from his home, telling them to notify the Fire Dept. The call was made to the Fire Dept. at 0720 hours.

b. There were no hose streams or fire extinguishers used on this fire since the fire was self-extinguished.

c. Recommendations and actions taken to prevent similar occurrences.

1. The flammable refrigerant and use in the copeland compressor is not restricted to the Calumet Freezers. Other freezer manufacturers use the same compressor and refrigerants. As noted in this report, an identical fire occurred in a Revco Freezer recently on this installation. Investigation has revealed other incidents with freezers resulting in fires and in some cases, no fire although the gas escaped. Attempts are being made to use alternate refrigerants that are non-flammable and yet will achieve the ultra-cold temperatures required for the materials used in research. Additionally, the electrical connection fault that occurs is due to an electromagnetic relay problem that warrants further examination. One solution is to replace all units on a regular basis since they are available in the Federal Supply System @ a cost of \$10.41 each. Since the combined problem is not resolved at this point in time the best course of action is to alert the Medical, Scientific, Research and Development Activities of the potential fire threat of low temperature freezers using the flammable refrigerant and the possibility of flash fires at the hermetic seal where the 208v. connection is made to the compressor. A follow-up report will be submitted on the work with alternate refrigerants and possible field modifications to the freezers. Separate report is in progress in USAMRIID to go to the Medical Dept. and to report equipment deficiencies thru the proper Army channels.

2. Fire Detection in Bldg. 1425 - The entire bldg. has no detection and is equipped with manual break stations throughout Phase I & II. The bldg. was built by contract thru Baltimore Dist. C. of E. The Baltimore Dist. is therefore in the best position to comment on the reasons for no detection. USAMRIID has initiated a work order to Facilities Engineering Fort Detrick on the feasibility of installing heat or smoke detection in the entire bldg. Preliminary information based on the size of the bldg. and the complexity of the Research functions with Lab. suites and animal holding areas indicates the need for extensive study and evaluation of areas by hazard to provide detection in the Bldg. Regardless, the cost of installation will be high because of the construction of the Bldg.

d. Location of the fire in the Bldg. is given in attached floor plan, Incl 3.

Jack E. Gray

JACK E. GRAY

Chief, Fire Prevention
and Protection Division

MILITARY POLICE REPORT		MILITARY POLICE (REP) NO.		REPORT NO.		CROSS REF. AND REPT NO.	
For use of this form see AF 100-20, 100-20-1, 100-20-2, 100-20-3, 100-20-4, 100-20-5, 100-20-6, 100-20-7, 100-20-8, 100-20-9, 100-20-10, 100-20-11, 100-20-12, 100-20-13, 100-20-14, 100-20-15, 100-20-16, 100-20-17, 100-20-18, 100-20-19, 100-20-20, 100-20-21, 100-20-22, 100-20-23, 100-20-24, 100-20-25, 100-20-26, 100-20-27, 100-20-28, 100-20-29, 100-20-30, 100-20-31, 100-20-32, 100-20-33, 100-20-34, 100-20-35, 100-20-36, 100-20-37, 100-20-38, 100-20-39, 100-20-40, 100-20-41, 100-20-42, 100-20-43, 100-20-44, 100-20-45, 100-20-46, 100-20-47, 100-20-48, 100-20-49, 100-20-50, 100-20-51, 100-20-52, 100-20-53, 100-20-54, 100-20-55, 100-20-56, 100-20-57, 100-20-58, 100-20-59, 100-20-60, 100-20-61, 100-20-62, 100-20-63, 100-20-64, 100-20-65, 100-20-66, 100-20-67, 100-20-68, 100-20-69, 100-20-70, 100-20-71, 100-20-72, 100-20-73, 100-20-74, 100-20-75, 100-20-76, 100-20-77, 100-20-78, 100-20-79, 100-20-80, 100-20-81, 100-20-82, 100-20-83, 100-20-84, 100-20-85, 100-20-86, 100-20-87, 100-20-88, 100-20-89, 100-20-90, 100-20-91, 100-20-92, 100-20-93, 100-20-94, 100-20-95, 100-20-96, 100-20-97, 100-20-98, 100-20-99, 100-20-100		325-81-200		81-07-23			
FROM:		TO:		FROM:			
		DFE Fort Detrick, MD		Security Directorate Fort Detrick, MD			
1. REPORT TYPE/STATUS							
2. EVALUATION							
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Report of Fire							
4. COMPLAINT RECEIVED BY (Name, grade, position)							
SOLICH, Donald J., 1LT, Actg DSEC							
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At 0430 hrs, 23 Jul 81, SMITH, while monitoring an alarm panel for Building 1425 observed BP Jack #23 activate indicating a loss of temperature to a freezer in Room #753, Bldg 1425. Due to the freezer alarm HASTY was called and upon his arrival at approximately 0700 hrs, he observed (cont'd)							
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DA FORM 3975

THIS FORM TOGETHER WITH DA FORM 2875-1, 1 JAN 74 REPLACES DA FORM 2875, 1 NOV 73 AND DA FORM 10-32, 1 SEP 60 WHICH ARE OBSOLETE.

GPO : 1980-318-671

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NEW DOD DIRECTIVES



DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
FORT DETRICK, FREDERICK, MD. 21701-5012



REPLY TO
ATTENTION OF

SGRD-ACQ (310)

24 May 1988

Command Policy 88-05

SUBJECT: Management of Hazardous Biological Materials

1. Purpose. To establish policy and procedures for management of RDTE Hazardous Biological Materials. This policy should be considered interim guidance pending revision to Chapter 3 of AR 70-65 on RDTE Hazardous Biological Materials.

2. Applicability. To Headquarters, U.S. Army Medical Research and Development Command (USAMRDC), all its subordinate units, extramural contractors, and other Government activities supported by USAMRDC.

3. Responsibility.

a. Commander, USAMRDC, is responsible for establishing command policy and ensuring that procedures are in place for the control and safe use of RDTE Hazardous Biological Materials.

b. Research Area Director, Military Disease Hazards Research Program, is responsible for coordinating the management and administration of the RDTE program involving hazardous biological materials.

c. The USAMRDC safety officer is responsible for coordinating policy with USAMRDC laboratories and other Government agencies, and for providing oversight of USAMRDC's safety programs.

d. The safety office within the USAMRDC Institute/Laboratory, in its special staff capacity, is responsible to the Institute/Laboratory Commander for in-house laboratory safety.

4. General. This policy augments Chapter 3, Army Regulation 70-65 Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities.

5. Procedures.

a. Appropriate procedures will be established to ensure that institutions and individuals, both in-house and extramural, maintain vigilance in assuring full compliance with the regulatory

SGRD-ACQ

SUBJECT: Management of Hazardous Biological Materials

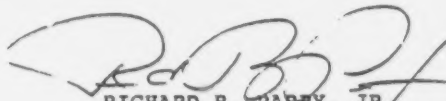
standards and policies regarding the handling, use, and control of hazardous biological materials with specific emphasis on safety and training.

b. All research activities utilizing hazardous biological materials and supported by USAMRDC will comply with the guidelines in the U.S. Department of Health and Human Services publication entitled Biosafety in Microbiological and Biomedical Laboratories, dated March 1984, as amended. For all contracts/grants/intragovernment orders specific provisions will be included concerning the standards and policies for the use of biological materials.

c. The proponent institute/laboratory safety office will conduct a preaward inspection of extramural research to be conducted in contractor and other Government laboratories at biosafety levels 3-4. The safety office will also conduct annual inspections of biosafety level 3 contractors or recipients, and semi-annual inspections of biosafety level 4 contractors or recipients. CORs assigned to monitor extramural research will be trained in biosafety level 1-4 procedures; the COR monitors compliance at all levels during site visits.

d. Prior to final award, the contractor or recipient of USAMRDC funds will provide, for Government approval, a facility safety plan addressing specific laboratory equipment, procedures, and general laboratory safety.

FOR THE COMMANDER:



RICHARD B. PARRY, JR.
Major, MS
Secretary of the General Staff

DISTRIBUTION:

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DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING

WASHINGTON, DC 20301-3010

15 JUN 1999

(R&AT)

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (RESEARCH,
DEVELOPMENT AND ACQUISITION)
ASSISTANT SECRETARY OF THE NAVY (RESEARCH,
ENGINEERING AND SYSTEMS)
ASSISTANT SECRETARY OF THE AIR FORCE (ACQUISITION)

SUBJECT: Policy on DoD Research Activities in the Biological
Defense Research Program

Reference is made to the US Department of Health and Human Services, Public Health Service Centers for Disease Control/National Institutes of Health publication entitled "Biosafety in Microbiological and Biomedical Laboratories."

This publication describes combinations of standard and special microbiological practices, safety equipment, and facilities that constitute biosafety levels 1-4 which are required to be followed when performing research in all phases of the Biological Defense Research Program. In addition, construction of new laboratory facilities and renovation of existing facilities shall comply with practices noted in this publication. Similar guidance should be included in all research contracts which form a part of the Biological Defense Research Program.

Application of recommendations in the publication to a particular laboratory operation should be based on a technical assessment of the specific agents and activities rather than as a universal and generic code applicable to all situations.

Following this policy will assure that all research activities are in compliance with this presently voluntary guide and meet all laboratory biosafety requirements.

Robert C. Duncan

POST-HEARING LETTERS

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United States Senate

COMMITTEE ON
 GOVERNMENTAL AFFAIRS
 SUBCOMMITTEE ON
 OVERSIGHT OF GOVERNMENT MANAGEMENT
 WASHINGTON, DC 20510-6250

August 23, 1988

Dr. Thomas J. Welch
 Deputy Assistant to the Secretary of Defense
 (Chemical Matters)
 Room 3E1074, The Pentagon
 Washington, D.C. 20301-3050

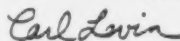
Dear Dr. Welch:

Thank you for your testimony and the testimony of your colleagues on July 28, 1988, before the Subcommittee on Oversight of Government Management. The information your panel provided was very helpful in addressing safety issues affecting research related to chemical warfare and chemical and biological defense.

To assist the Subcommittee in gaining a complete understanding of DOD's testimony and position on these safety issues, we have a number of follow-up questions. Those questions are attached. We would appreciate your providing a written response to them by September 13, 1988.

Thank you for your assistance in this important matter. We look forward to working with you on resolving the safety issues raised at the hearing, and we are pleased with your demonstration of interest and cooperation in this area. If you have any questions, please have your staff contact Elise J. Bean of the Subcommittee staff at (202) 224-3682.

Sincerely,



Carl Levin
 Chairman



William S. Cohen
 Ranking Member

CL/WSC:ejb
 Enclosure

INSERT FOR THE RECORD					
HOUSE	APPROPRIATIONS COMMITTEE	HOUSE	ARMED SERVICES COMMITTEE	HOUSE	OTHER SGA/Scte on
SENATE		SENATE		X SENATE	Oversight of GA
HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	DoD Safety Program for Chem Bio Defense Res	
29 July 1988			Question #1		

CHANGE OF DR. WELCH'S TITLE

Question. At the hearing, Dr. Welch testified that responsibility for the Biological Defense Program (BDP) was not explicitly included within his charter and that he would take steps to correct that deficiency. What steps have been or will be taken? Will Dr. Welch's job title, Deputy Assistant to the Secretary of Defense (Chemical Matters), be changed to reflect his broader responsibilities? Please provide copies of any documentation.

Answer. DoD Directive 5148.2, Assistant to the Secretary of Defense (Atomic Energy), defines the responsibilities and functions of the ATSD(AE). Since the Deputy Assistant to the Secretary of Defense (Chemical Matters) reports to the ATSD(AE), DoDD 5148.2 applies to him as well. The directive was revised in May 1988 and is still in coordination. The revision includes specific guidance concerning the biological defense program. We will provide the subcommittee with a copy upon publication. Changing Dr. Welch's title to include biological defense matters would serve little purpose as his charter gives him the necessary authority.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	DoD Safety Program for Chem Bio Warfare	
July 28, 1988			Question #2		

OSHA OVERSIGHT

Question. At the hearing, Dr. Welsh testified that DoD would, for the first time, invite the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH) to evaluate safety practices and to conduct safety inspections of DoD's in-house CBW research facilities.

(a) When will this invitation be issued? If it already has been issued, please provide a copy.

(b) Will DoD invite OSHA and NIOSH to conduct routine, periodical safety inspections of DoD's CBW research facilities, in addition to any ad hoc or special inspections? Please describe the contemplated arrangement.

(c) Please explain what additional procedural steps DoD intends to take to implement plans for OSHA/NIOSH inspections of its CBW research facilities, including any steps necessary to reconcile these plans with DoD Instruction 6055.1 (1984) which generally requires DoD Components to comply with OSHA and NIOSH safety standards and to permit OSHA safety inspections, but which exempts "military unique workplaces" from these requirements.

(d) Please identify the DoD official overseeing implementation of DoD's plans in this area, and provide copies of any relevant documentation.

Answer. Notwithstanding the language in Executive Order 12196, "Occupational Safety and Health Program for Federal Employees" and DoD Instruction 6055.1, "Department of Defense Occupational Safety and Health Program" concerning "uniquely military equipment, systems, and operations," DoD has no objection to OSHA providing safety oversight of DoD chemical warfare and chemical/biological defense (CW/CBD) research. Consequently, on August 9, 1988, a meeting of DoD and OSHA officials was held concerning possible OSHA inspections of DoD in-house and contractor CW/CBD research facilities. As a result of that meeting a formal letter of request for assistance was sent to OSHA. A copy is provided under separate cover. Mr. George W. Siebert, Director of Safety and Occupational Health Policy, in the Office of the Secretary of Defense, is DoD's principal point of contact on this issue.



THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301-4000

7 Sep 1988

FORCE MANAGEMENT
AND PERSONNEL

Honorable John A. Pendergrass
Assistant Secretary of Labor
for Occupational Safety & Health
U.S. Department of Labor
Washington, D.C. 20210

Dear Mr. Pendergrass:

During recent hearings held by the Senate Committee on Governmental Affairs, Subcommittee on Oversight of Government Management, concerning the Department of Defense's safety programs for chemical warfare and chemical/biological defense (CW/CBD) research, we were asked to consider the feasibility of regular (at least annually) safety inspections of these programs by another Federal agency. The Subcommittee expressed the belief that such an outside oversight role by a qualified Federal agency would serve to reassure the public that these essential defense programs were being conducted in the safest manner practicable. The Occupational Safety and Health Administration (OSHA) was identified as a possible candidate for such a role.

As you know, OSHA has not provided safety oversight of DoD CW/CBD research operations since they have been considered to be "military unique" pursuant to Executive Order 12196, "Occupational Safety and Health Programs for Federal Employees." We, however, have no objection to OSHA providing assistance in evaluating the safety of CW/CBD research activities. CW/CBD research is conducted at the following DoD facilities:

- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, MD
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, MD
- U.S. Army Chemical Research, Development & Engineering Center (CRDEC), Aberdeen Proving Ground, MD
- U.S. Army Dugway Proving Ground, Utah

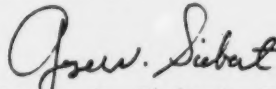
Since the majority of CW/CBD research is, however, conducted by DoD contractors, the Subcommittee was particularly interested in the establishment of an outside oversight inspection program for those facilities. Such inspections would be in addition to the present inspection program already being provided by the Department of Army (the executive agent of the Department of Defense for these research programs). Currently about 130 different DoD contractors are involved with these research programs as follows:

<u>Type of Research</u>	<u>Orientation of Research</u>	
	<u>Medical</u>	<u>Non-Medical</u>
Chemical Agents	50	10
Biological Agents	60-80	-

I would appreciate your views on whether OSHA can perform this independent oversight function. Upon your concurrence, we will provide to OSHA a list (and locations) of all DoD contractors performing CW/CBD research for on-site inspections. We would also appreciate OSHA's technical assistance to review our regulations and procedures in use, or in preparation, to help ensure CW/CBD research safety.

Please have your staff contact me on (202) 695-0110 if I can provide any additional information. Thank you for your assistance.

Sincerely,



George W. Siebert, CIH
Director for Safety and
Occupational Health Policy

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.			BOD Safety Prog	
28 July 1988			Question #3			For Chem Bio/WARF	

Army Inspector General Report

QUESTION: The Army Inspector General, in a June 27, 1988, report on chemical safety, made a number of recommendations to address weaknesses in the Army's implementation of its chemical surety safety program. What is the Army's response to this report and its recommendations? Please provide copies of any written response to the Inspector General's report.

ANSWER: Six major recommendations were identified at the Army level in the Inspector General (IG) safety program report. Two recommendations were made at the major Army command level, and one recommendation was identified for the Project Manager for Chemical Demilitarization.

In response to these recommendations, the Director of Army Safety developed an Implementation Plan to address the specific recommendations in the IG report. The Implementation Plan identified the specific tasks required to accomplish the IG recommendations, and established milestone dates for completion of these tasks. A copy of the implementation plan is provided under separate cover.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	DoD Safety Program for	
July 28, 1988			Question #4	Chem Bio Warfare	

CHEMICAL SAFETY REGULATION

Question. Several DoD witnesses at the hearing referred to a new regulation on chemical safety. Please indicate the status of this regulation and provide a copy of the latest draft or the final version.

Answer. On July 9, 1987, DoD Instruction 4120.13, "Safety Program for Chemical Agents and Weapon Systems" was issued. A copy of that Instruction is provided under separate cover. It requires that the DoD Component responsible for any phase in the life cycle of a chemical weapon system establish and maintain a chemical agent safety program as an element of its overall safety and occupational health program to protect:

- o DoD personnel from accidental injury or death during weapons research, development, testing, production, transportation, storage, deployment, and disposal.

- o The public and the environment from adverse effects.

It also requires unbiased and periodic system safety reviews and describes the minimal elements of a chemical agent safety program; e.g., education, staffing, protective equipment, engineering controls, reporting, etc. A copy of the Army implementing regulation, AR 385-61, "The Army Safety Program for Toxic Chemical Weapons" will be provided. It is anticipated to be published in the 2nd quarter of FY 89.

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Department of Defense INSTRUCTION

July 9, 1987
NUMBER 4120.13

ASD (FM&P)

SUBJECT: Safety Program for Chemical Agents and Weapon Systems

- References: (a) DoD Instruction 4120.13, "Safety Program for Chemical Agents and Associated Weapon Systems," April 30, 1970 (hereby canceled)
- (b) JCS Pub. 1, "Department of Defense Dictionary of Military and Associated Terms," April 1, 1984, authorized by DoD Directive 5000.9, March 23, 1981
- (c) DoD Instruction 6055.1, "DoD Occupational Safety and Health Program," October 26, 1984
- (d) DoD Directive 1000.3, "Safety and Occupational Health Policy for the Department of Defense," March 29, 1979
- (e) through (i), see enclosure 1

A. REISSUANCE AND PURPOSE

This Instruction reissues reference (a) to update DoD policies and procedures and assigns responsibilities for minimizing the potential and severity of DoD chemical agent accidents through the application of safety management and system safety principles.

B. APPLICABILITY AND SCOPE

This Instruction:

1. Applies to chemical agents and associated weapon systems, including binary chemical agent weapon systems. All such items are hereafter referred to collectively as "chemical weapon systems."
2. Applies to chemical weapon systems research and development, production, storage, decontamination, and demilitarization facilities.
3. Does not apply to riot control or smoke agents, herbicides, or flame generating systems.
4. Applies to Military Departments and Defense Agencies (hereafter referred to collectively as "DoD Components") responsible for any phase in the life cycle of a chemical weapon system.

C. DEFINITIONS

1. Chemical Agent. A chemical substance which is intended for use in military operations to kill, seriously injure, or incapacitate man through its physiological effects. Excluded from consideration are riot control agents, herbicides, smoke, and flame. (This definition is taken from reference (b).)

2. Binary Chemical Agent Weapon System. A weapon system that contains two relatively nontoxic chemicals that combine during functioning of the weapon system to produce a chemical agent for release on target.

D. POLICY

1. DoD Components responsible for any phase in the life cycle of a chemical weapon system shall establish and maintain chemical agent safety programs and procedures as an element of their overall safety and occupational health program under DoD Instruction 6055.1 (reference (c)) to protect:

a. DoD personnel from accidental injury or death during weapons research, development, testing, production, transportation, storage, deployment, and disposal.

b. ~~The~~ public and the environment from adverse effects.

2. Chemical weapon systems shall be given unbiased and periodic system safety reviews.

E. RESPONSIBILITIES

1. The Assistant Secretary of Defense (Force Management and Personnel), in accordance with DoD Directive 1000.3 (reference (d)), is responsible for the DoD Safety and Occupational Health Program, of which chemical agent safety policy is an element.

2. The Assistant Secretary of Defense (Production and Logistics), in accordance with DoD Directive 5100.50 (reference (e)), is responsible for policy and management oversight for environmental issues.

3. The Assistant To The Secretary of Defense (Atomic Energy), in accordance with DoD Directive 5148.2 (reference (f)), is responsible for overall chemical agent matters.

4. DoD Components establishing or maintaining chemical agent safety programs in accordance with this Instruction shall:

a. Evaluate the safety of chemical weapon systems, equipment, facilities, and the adequacy of safety rules and/or procedures and training.

b. Systematically eliminate or control hazards in chemical weapon systems, equipment, and facilities primarily through engineering design and controls and secondarily through procedural controls.

c. Educate personnel on the risks associated with chemical agent operations.

d. Monitor the health and work environment of occupationally-exposed personnel.

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e. Obtain or develop in accordance with DoD Directive 5160.5 (reference (g)) protective clothing and equipment, monitoring and/or detection equipment, and decontamination capability necessary to meet the occupational exposure standards under DoD 6055.9-STD (reference (h)).

f. Implement DoD Explosives Safety Board standards (DoD 6055.9-STD, reference (h)).

g. Establish contingency planning to include chemical accident and/or incident (CAI) response and assistance, CAI reporting and investigation in accordance with DoD 6055.9-STD (reference (h)), and public affairs planning.

h. Include chemical weapon systems, chemical agent protective clothing and equipment, monitoring and/or detection equipment, and other equipment and facilities in their system safety program required by DoD Instruction 5000.36 (reference (i)).

i. Ensure that unbiased system safety reviews of their chemical weapon systems are accomplished.

5. Each DoD Component responsible for development of a chemical weapon system shall:

a. Establish a system safety review process.

(1) For chemical weapon systems being developed, a system safety study shall be conducted during each materiel acquisition phase and shall be available 90 days before each milestone review and scheduled deployment (see enclosure 2). These studies shall assess the safety of the weapon system and its compliance with safety standards; shall identify findings and make recommendations. The recommendations shall be used to assist decision-makers on whether or not to continue system development and what further development and system changes are required to meet established chemical agent safety standards, consistent with operational requirements. The recommendations also should address what safety and health information is necessary for any follow-on study, and desirable system changes to optimize safety characteristics. Study recommendations also should address what safety issues should be briefed at milestone reviews. The Production and Deployment Study also shall include recommendations for safety rules necessary to minimize hazards that might not be eliminated by design.

(2) Following operational experience with chemical weapon systems currently being developed, and for chemical weapon systems currently accepted for Service use (for which no previous system safety studies exist), a one-time Special Study shall be conducted. In either case, these studies shall evaluate the safety of the weapon systems during all remaining phases of their life cycles. The results shall be quantitative in nature, and shall include conclusions for the overall safety of the systems and specific recommendations that address all identified problem areas. They also shall document the safety lessons learned for application to future weapon systems development.

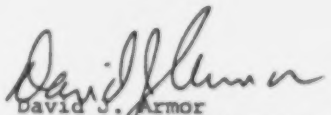
(3) Additional Special Studies should be conducted for all deployed chemical weapon systems, as required, to evaluate the impact on safety of changes in system design; production, maintenance, transportation, storage, use, or disposal methods; or other parameters.

(4) On completion, chemical weapon system safety studies and updates shall be provided to the Assistant to the Secretary of Defense (Atomic Energy) and to the Assistant Secretary of Defense (Force Management and Personnel).

b. Formally document in subsequent system safety studies each management decision to accept the risks associated with an identified hazard.

F. EFFECTIVE DATE AND IMPLEMENTATION

This Instruction is effective immediately. Forward one copy of implementing documents to the Assistant Secretary of Defense (Force Management and Personnel) within 180 days.


David J. ARMOR
Acting Assistant Secretary
of Defense (Force Management
and Personnel)

Enclosures - 2

1. References
2. System Safety Study Milestone Guide

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4120.13 (Encl 1)

REFERENCES, continued

- (e) DoD Directive 5100.50, "Protection and Enhancement of Environmental Quality," May 24, 1973
- (f) DoD Directive 5148.2, "Assistant to the Secretary of Defense (Atomic Energy)," February 4, 1986
- (g) DoD Directive 5160.5, "Responsibilities for Research, Development, and Acquisition of Chemical Weapons and Chemical and Biological Defense," May 1, 1985
- (h) DoD 6055.9-STD, "DoD Ammunition and Explosives Safety Standards," July 1984, authorized by DoD Directive 6055.9, November 25, 1983
- (i) DoD Instruction 5000.36, "System Safety Engineering and Management," April 14, 1986

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4120.13 (Encl 2)

SYSTEM SAFETY STUDY MILESTONE GUIDE

Timing of System Safety Studies for Chemical Weapon Systems Relative to Life Cycle Milestone Reviews

CONCEPTUAL STUDY

Conducted during the first stages of concept exploration and throughout research and development. Safety in all future phases of the life cycle should be considered during this and subsequent studies. Completed at least 90 days before Milestone I.

DEMONSTRATION AND VALIDATION STUDY

Builds on Conceptual Study, preliminary design and engineering, trade-off proposals, etc. Completed at least 90 days before Milestone II.

FULL-SCALE DEVELOPMENT STUDY

Builds on previous studies and safety data from advanced engineering, fabrication, and testing. Completed at least 90 days before Milestone III and system is accepted for service use.

PRODUCTION AND DEPLOYMENT STUDY

Builds on previous studies, results of production testing and evaluation, impact of preplanned product improvements, etc. Completed at least 90 days before scheduled deployment.

SPECIAL STUDY

Conducted after operational experience with chemical weapon systems and on current systems to determine whether system is safe for all aspects of remaining life cycle. Documents lessons learned for application to future systems development.

and

Conducted on all chemical weapon systems, as required to evaluate impact on safety of changes in system design; production, maintenance, transportation, storage, use, or disposal methods; or other parameters.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.		
28 July 1989			Question #5	DOD Safety Prog For Chem Bio/WARP	

APG AR 15-6 Findings

QUESTION: What is the status of the implementation of the recommendations of the Army's 15-6 board of inquiry regarding safety and environmental violations discovered at Aberdeen's chemical warfare research facilities? What is the status of negotiations between DOD and the State of Maryland regarding enforcement of safety and environmental rules by Maryland officials?

ANSWER: Of the 101 findings/recommendations, 80 have been verified as completed as of 24 August 1988. Of the 21 remaining findings/recommendations, corrective actions for all but eight will be initiated by 31 December 1988. The eight remaining are scheduled for corrective actions which will be initiated by the end of fiscal year 1989. It should be noted that of the 101 findings in the Board's report only one finding noted safety and environmental violations at active chemical warfare research facilities. This finding reported a total of 35 observations in four facilities. Thirty four of the 35 observations have been corrected and the remaining one observation is in the process of being corrected.

A consent Order between Maryland and APG was finalized on 24 August 1988. The Consent Order authorizes APG to resume incineration of decontamination solutions from chemical agents which was halted in January 1987 when Maryland declared them to be acute hazardous wastes; allows APG to store excess chemical agents in current, established areas pending modification of the permit for storing excess chemical agents; and to store hazardous wastes other than chemical agents pending action of APG's application for modification of its waste permit to allow for expanded storage in the permitted facility.

Negotiations are continuing between Maryland, DOJ, DA and APG on a Consent Judgement. It is anticipated that several issues will be covered including the development of a hazardous waste management plan, implementation of a training program, and a system to report progress to the State. Issues concerning funding and agency discretion are still pending DA and DOJ review. Further negotiations are required between the parties.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	DOD Safety Prog For Chem Bio/WARF	
28 July 1988			Question #6		

Contractor Safety Violations

QUESTION: At the hearing, a representative of the U.S. Army Chemical Research, Development and Engineering Center (CRDEC) promised to determine whether numerous safety violations committed by a certain chemical warfare research contractor had been corrected. What is the status of that effort?

ANSWER: A follow-up inspection conducted by CRDEC personnel on 11 Aug 88 revealed that all findings noted during the 14 Dec 87 inspection had been corrected, as previously certified by the contractor.

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29 July 1988			Question #7	DOD Safety Reg For Chem Bio/WART	

Central Biological Defense Safety Office

QUESTION: During the hearing, Dr. Welch testified that DOD was establishing a "Central Biological Defense Safety and Surety Office." Where will this office be located within the DOD command structure, who will be in charge of it, approximately how many staff positions will it have, and what specific safety functions will it perform? How will it relate to the Army Safety Office?

ANSWER: DOD Directive 5160.5, Responsibilities for Resource, Development, and Acquisition of Chemical Weapons and Chemical and Biological Defense, assigns to the Department of the Army Executive Agent responsibilities for the DOD chemical/biological defense program.

As the executive agent, the Director of Army Safety is an element of the Office of the Chief of Staff, Army, and is the central authority for all aspects of Safety, to include CW/CBDR. The responsibilities and functions of the Director of Army Safety for the CW/CBD research programs have been strengthened and are clearly delineated in draft DA Memo 5-XX, and draft chemical and biological safety regulations. The Director of Army Safety oversees a staff in the Army Safety Office, Wash. DC, and a large staff at the Army Safety Center, Ft Rucker, AL. Technical assistance is also available from the Army Staff, Army Medical R&D Command and the Army Materiel Command. These resources will be used to manage and oversee the CW/CBD research safety program. Copies of these documents will be provided when published.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.		DOD Safety Prog For Chem Bio/WARF
28 July 1988			Question #8		

Army Medical R&D Command Directive

QUESTION: On May 24, 1988, the Army Medical Research and Development Command issued a directive ordering the development of safety procedures for handling hazardous biological materials, requiring pre-award and routine safety inspections of laboratories performing BDP research, and requiring these laboratories to submit facility safety plans for DOD approval. The directive states that it provides "interim guidance" pending revision of an existing regulation.

(a) What is the status of the implementation of this directive? Who is responsible for overseeing its implementation?

ANSWER: The directive is being implemented for all new contracts involving hazardous biological materials, existing contracts are being modified as time permits. Since the directive deals with several areas of responsibility (e.g., acquisition, safety, management), there are several personnel within HQ, USAMRDC involved in the implementation of the directive. The pertinent safety provisions of this directive will be included in the draft biological safety regulation.

(b) Does this directive apply to all laboratories and contractors performing BDP research, without exception? Has it been circulated to all affected laboratories and contractors?

ANSWER: The directive applies to HQ, USAMRDC, all its subordinate units, extramural contractors, and other Government activities supported by USAMRDC. The Directive has been provided to all USAMRDC laboratories and is being incorporated into extramural contracts as expeditiously as possible.

The Assistant Secretary of the Army (Research, Development Acquisition) has issued interim message guidance to Army Commands and laboratories performing BD research.

(c) Is the regulation referred to in the directive to become the comprehensive BDP safety regulation discussed at the hearing? What is the status of that regulation and who is overseeing its revision? Will it apply to all laboratories and contractors performing BDP research, without exception? Will DOD consult with the Subcommittee on the substance of that regulation prior to its issuance?

ANSWER: USAMRDC is working with the Army Safety Office in the drafting and implementation of a comprehensive safety regulation for the BDP. The regulation is currently in draft form. The regulation will be applicable to BDP research performed by Army laboratories and contractors and other Government activities supported by the Army. If requested, the Army Safety Office will consult with the Subcommittee on the substance of the regulation prior to its issuance.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.		
July 28, 1988			Question 9	DoD Safety Program for C/B Research	

Policy on BRDP Safety

Question: On June 15, 1988, DoD Director of Research and Engineering, Robert Duncan, issued a service-wide directive entitled, "Policy on DoD Research Activities in the Biological Defense Research Program". This Directive made the biosafety guidelines promulgated by the Centers for Disease Control and the National Institutes of Health mandatory for all participants in the Biological Defense Program.

(a) Who is responsible for overseeing the implementation of this directive? Has it been circulated to all affected laboratories and contractors?

(b) How will DoD ensure that BDP laboratories comply with these mandatory safety rules?

Answer: The directive was issued to the Assistant Secretaries for Research and Development of all the Military Departments for action and implementation. Each Military Department will provide their own oversight through their normal review system just as they review the Recombinant DNA guidelines for compliance. Contractors will be reviewed by the Contracting Officers Technical Representative for compliance. The principal performer of the Biological Defense Research Program, the Department of the Army, has already provided this policy to all Army Commands by message for implementation. The Office of the Secretary of Defense staff intends to monitor this action to ensure implementation and compliance.

INSERT FOR THE RECORD					
HOUSE	APPROPRIATIONS COMMITTEE	HOUSE	ARMED SERVICES COMMITTEE	HOUSE	OTHER SGA/Scte on Oversight of GA
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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.		
July 28, 1988			Question 10	DOD Safety Program for C/B Research	

Army Board of Inquiry Documents

Question: During the hearing, Col. Huxsoll agreed to provide copies of certain documents to the Subcommittee. These documents were identified as: a 1986 report by an Army 15-6 board of inquiry which investigated the 1981 incident in which viral materials were found missing from USAMRIID; an October 1986 "addendum" to a memorandum dated December 30, 1981, in which a USAMRIID employee may indicate that she may have autoclaved the missing viral material; and a 1981 report by the Fort Detrick fire department on a 1981 fire that occurred in Dr. Levitt's laboratory. Please provide copies of these documents.

Answer: These documents have been provided to the Subcommittee by the Army Legislative Liaison.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	DOD Safety Program for C/B Research	
July 28, 1988			Question 11		

Safety of Junin Vaccine

Question: Testimony was provided at the hearing that human volunteers are being inoculated with a new, DOD-developed Junin vaccine which was produced with a cell line that a former researcher believes may be contaminated. Col. Huxsoll testified that this vaccine and the associated cell line had been tested and found free of contamination. He promised to provide copies of these tests. Please include them with your response.

Answer: The requested test results have been provided to the Subcommittee by the Army Legislative Liaison.

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28 JUL 88			QUESTION #12	DOD SAFETY PROGRAM FOR CHEM/BIO/WARFARE	

YALE UNIVERSITY

Question: At the hearing, questions were raised about safety practices and procedures at Yale University regarding its handling of two BDP contracts. Has DoD evaluated or is it planning to evaluate Yale's safety operations? How often will DoD conduct safety inspections of Yale's research facilities?

Answer: The Yale Arbovirus Research Unit (YARU) was inspected on July 14, 1988. This inspection covered both general laboratory safety and safety of Biosafety Level 3 (BL-3) operations. No violations were observed pertaining to general laboratory safety. BL-3 operations were in compliance with Centers for Disease Control guidelines. Following your July 27, 1988 hearings, Army and YARU officials discussed the critical relationships between assurance of laboratory safety and continued Army contract support.

As required by the U.S. Army Medical Research and Development Command, contract BL-3 laboratories are inspected annually and BL-4 laboratories are inspected semi-annually. Normally, Yale would be inspected on an annual basis with its next scheduled inspection to be completed prior to July 14, 1989. Because of the visibility of the YARU and its critical role in the Biological Defense Research Program, a follow-up of the July 14, 1988 inspection will be conducted within the next six months.

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28 JULY 88			QUESTION #13		

ARMY SCIENCE BOARD REPORT

Question: An Army Science Board report of July 1987 contains criticism of the Army's CBW research program. What specifically has DoD done to respond to the management and organizational shortcomings raised by the Board? The Board noted a deficiency in the educational credentials of professional personnel assigned to the CRDEC at Aberdeen. What has been DoD's response to this criticism?

Answer: The Program Executive Officer for Chemical Nuclear (PEO C/N) has appointed a biotechnologist to his staff to effect coordination at various echelons. The Commanding General, Chemical Research, Development, and Engineering Center has hired a Biotechnologist as an advisor. Biological Defense Coordinators have been named at various staffs levels. The Army Science Board did not criticize the educational credentials of professional personnel assigned to the CRDEC; it criticized the shortage of people trained in biotechnology. To improve this condition, CRDEC has filled eight microbiology/biotechnology/toxicology positions, to include a new senior command-level special advisor on biotechnology (an SES equivalent) positions.

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July 28, 1988			Question 14	DoD Safety Program for C/R Research	

Liability of Contractors

Question: Under the Federal Acquisition Regulation, DoD requires CBW research contractors to obtain certain liability insurance. What consultation, if any, does DoD undertake with the insurers of its CBW contractors? What liability does the federal government have in the event of an accident or incident involving one of its contractors performing research related to chemical or biological warfare?

Answer: The DoD does not generally consult with the insurers of its contractors; our contact is only with the contractors themselves. Liability of the federal government can only be dealt with on a case by case basis after a review of the facts in a particular case. I must point out that the DoD performs only a biological defense research program; biological warfare is precluded by national policy.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.		
28 July 1988			Question #15(1)	DOD Safety Prog For Chem Bio/WARF	

Chemical and Biological Safety Program

QUESTION: At the beginning of the hearing, in Senator Levin's opening statement, a number of possible improvements in DOD's CBW safety programs were suggested. Please provide DOD's response to these suggestions.

Suggestions for Both Chemical and Biological Research Programs:

1. Assign the roll of coordinating the safety programs in the two portions of the CBW research program to the Army Safety Office or equivalent body.

ANSWER: The Director of Army Safety (DASAF) is responsible for all aspects of Army safety, to include the CW/CBD research program. Army Regulation (AR) 385-10, The Army Safety Program, 23 May 88, assigns the DASAF the responsibility to "administer and direct an effective Army safety program to reduce the occurrence of accidents". The DASAF is responsible for developing, coordinating and disseminating Army safety program policy, direction and guidance.

DA Memo 5-XX, Management of Space and Special Weapons, which has been staffed and is now awaiting signature, further clarifies and delineates the DASAF responsibilities. The memo assigns the following DASAF responsibilities:

(a) Establish personnel safety policy standards and procedures for chemical agent and weapons systems and biological material.

(b) Review chemical agent and biological safety programs of major Army commands to ensure compliance with DA policy.

(c) Coordinate and approve requests for waivers and exemptions to personnel safety policies.

The Army Safety Office has assumed responsibility for coordinating the safety programs for biological and chemical research. Responsibilities and safety policies will be dictated to Army agencies conducting CW/CBD research through the 385 (safety) series of regulations. These regulations are applicable to all Army Commands, organizations, agencies and contractors. This includes organizations conducting defensive research against potential chemical and biological agents. Two regulations, one a revised, expanded regulation for chemical agent safety, and the other a new one for biological defense research safety, are being completed. These regulations will require Army organizations engaged in CW/CBD research to seek Army Safety Office approval on all actions that imply or establish a DA Safety position. DA will review all MACOM & agency CW/CBDR safety programs on an as needed, at least, annual, basis.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	DOD Safety Prog For Chem Bio/WARF		
28 July 1988			Question #15(2)			

Safety Training

QUESTION: Mandate appropriate safety training for scientists and other laboratory personnel, such as technicians, clericals and maintenance workers.

ANSWER: Safety training is currently required by Army regulations (e.g., AR 385-64 and AR 50-6 for chemical agents and AR 385-10, Chapter 3-1a for Hazard Communication) and implemented by supporting policies at the command and performing organization/institution level. Content and frequency of appropriate safety training requirements will be contained in Chapters 2 and 4 of the chemical regulation; similarly, the biological defense safety regulation will address appropriate safety training for contract and in-house scientists, as well as technical and supporting personnel in the biological defense program.

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28 July 1988			Question #15(3)	DOD Safety Prog For Chem Bio/WARF	

Notification of Fire Departments

QUESTION: Require CBW labs to: (a) notify their local fire departments of any highly toxic or infectious agents which will be on the premises, prior to placing them on the premises, and (b) submit with their safety plans a specific plan for fighting any fires at the facility, after obtaining the agreement and signature of the local fire department chief.

ANSWER: DA will dictate this requirement to all Army Commands, organizations, agencies. and contractors through the AR 385 series. The 385 Regulations will require all Army agencies engaged in CW/CBD research to submit their safety & notification plans to their servicing fire department and obtain a letter of agreement. These plans will include recommended procedures for combating potential fires. Letters of agreement will be reviewed on an annual basis.

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28 July 1988				DOD Safety Prog For Chem Bio/WARF	

Safety Concerns of Scientists and Workers

QUESTION: Address the safety concerns not only of scientists, but also other laboratory personnel, such as technicians, clericals and maintenance workers.

ANSWER: Laboratory safety concerns for all personnel ancillary to CW/CBD research will be addressed in the draft chemical and biological safety regulations. Ongoing Army implementation of the Hazard Communication Program will also aid in the education of these workers.

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28 July 1988			Question #15 (5)	DOD Safety Prog for Chem Bio/WARP	

Protection for Whistleblowers

QUESTION: Provide protection for whistleblowers who report unsafe conditions or practices in labs conducting CBW research, by developing new protective measures or referencing existing procedures.

ANSWER: Military and civilian employees are entitled to present complaints of unsafe or unhealthful working conditions through the Inspector General (IG) network under the protection afforded by AR 20-1, Inspector General Activities and Procedures, dated 16 September 1986, Chapter 4, section 4-3, Rights of Individuals, as well as AR 600-20, Army Command Policy, section 5-8, Complaints against Military Personnel. Contractors are afforded similar complaint channels through the DOD Hotline system (DOD Directive 7050.1)

Whistleblower protection is also afforded employees via Public Law 91-596 and 29 CFR Part 1960 and 1910. These regulations and laws clearly state that employees will not be subject to restraint, interference, coercion, discrimination or reprisal for filing a report of an unsafe or unhealthy working condition.

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28 July 1988			Question #15(6)		

Federal Agency Inspection of CB Facilities

QUESTION: Establish a system in which a federal agency with expertise in safety, other than DOD, will conduct at least annual safety inspections of DOD CBW research facilities and file its written findings with the Army Safety Office.

ANSWER: See committee question 2 for response.

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28 July 1988					DOD Safety Prog for Chem Bio/MARF		

Aberdeen Board of Investigation

Suggestions For the Chemical Warfare Research Program:
 QUESTION: Implement all 100 recommendations of the special board of investigation at Aberdeen, including the reorganization of its safety offices, increase in safety training, improvement in chemical casualty emergency plans, and improvement in environmental practices.

ANSWER: See committee question 5 for response.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	Question #15(3)	
28 July 1988				For Chem Bio/WARF	

Contractor Inspection Requirements

QUESTION: Apply the CRDEC requirement, to conduct semi-annual inspections of contractors using high risk chemical agents, to all labs conducting high risk CW research, including those monitored by the Institute for Chemical Defense.

ANSWER: All contract sites using high risk (neat) chemical agents are inspected semi-annually. Contract sites using dilute solutions are inspected annually because the hazard associated with the dilute agent is greatly reduced. In addition, contract clauses require that contractors certify they are not delisted by EPA (i.e., have been demonstrated to pollute the environment) and that they will adhere to the Clean Air and Water Acts (FAR 52.223-1 and FAR 52.223-2).

Chapter 4 of the draft chemical safety regulations requires that an inspection schedule for all contractors will be established by the contracting agency. The schedule will include the following:

- (1) A pre-award inspection on site prior to the contract award.
- (2) A pre-award inspection of follow-on contracts.
- (3) If during the pre-award inspection, major corrective measures are required, a reinspection must be conducted prior to shipment of agent.
- (4) A pre-operational inspection if a major change in procedures or equipment is made after the pre-award survey.
- (5) Semi-annual inspections of neat agent contractors' facilities and operations and annual inspection of dilute solution contractors.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	DOD Safety Prog	
28 July 1988			Question #15(4)	For Chem Bio/WARF	

Safety Inspection Reports

QUESTION: Revise the safety inspection reports and any necessary procedures to ensure that identified safety violations are corrected and to document the corrective actions actually taken.

ANSWER: Army Guidance and safety inspection reporting and follow-up procedures concerning chemical agent research will be contained in 385 series documents.

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28 July 1988			Question #15(5)		DOD Safety Prog For Chem Bio/WARF

Contractor Penalties

QUESTION: Develop a system of contractor penalties, short of contract termination, which will discourage unsafe conditions and practices.

ANSWER: Contracting officer's technical representatives, and contracting officers, make every effort to educate contractors in required safety procedures and to assist in correcting deficiencies. Contract termination is considered only when the contracting organization demonstrates an inability or unwillingness to comply with safety requirements. Withholding of incremental funding, stop work orders or monetary penalties as invoked in materiel procurement contracts are not realistic options in research, cost-reimbursement contracts. The Army will continue to pursue this issue.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.	DOD Safety Prog	
28 July 1988			Question #15(1)	For Chem Bio/WARF	

Biological Defense Program Title

Suggestions for the Biological Defense Program:
 QUESTION: Reflect the authority and responsibility for the
 Biological Defense Program in the titles of the Deputy Assistant
 Secretary for Chemical Matters and other appropriate officials.
 ANSWER: See committee question 1 for response.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.		
28 July 1988			Question #15(2)	DOD Safety Prog For Chem Bio/WARF	

Biological Safety Regulation

QUESTION: Publish a comprehensive safety regulation that will apply to all labs conducting BDF research, without exception. In developing the safety regulation, solicit suggestions from safety experts and concerned parties.

ANSWER: The Army Safety Office in coordination with the Army Staff and Major Army Commands is developing a biological safety regulation and a DA Pamphlet. The regulation will define policy, applicability, responsibilities, program elements, contractor operations, review of safety submission, inspections, etc. A DA Pamphlet will contain the technical biological safety standards which will, as a minimum, follow CDC/NIH guidance. Input from safety experts in the biological field will be solicited prior to publication of regulation and pamphlet. Estimated date of publication is 4th Quarter FY89.

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28 July 1988			Question #15(3)			For Chem Bio/WARF

Inspection Checklist

QUESTION: For pre-award and subsequent safety inspections, use a checklist and safety inspection report which will document the particular items checked and any safety violations found. Implement mechanisms which will ensure that identified safety violations are corrected and document the corrective measures taken. Conduct an annual accident drill for BL3 and 4 facilities.

ANSWER: A draft checklist, reporting and follow-up procedures for biocontainment laboratory safety inspection has been developed. The checklist covers general laboratory safety, as well as specific features of biosafety level 2, 3 and 4 laboratories. The inspection procedures will be formalized in the biological safety regulation.

Similarly, inspections and an annual exercise of contractor accident response plan will be mandated in the draft biological safety regulation.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.		
8 July 1988			Question #15(4)	DOD Safety Prog For Chem Bio/WARF	

Safety Audits

QUESTION: Require all CBW labs to certify their compliance with applicable safety rules and to disclose any important safety audits or safety problems they have experienced within the preceding 5 years.

ANSWER: Stringent inspection and compliance requirements will be contained in both the draft chemical and biological safety regulations.

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HEARING DATE	TRANSCRIPT PAGE NO.	LINE NO.	INSERT NO.		
28 July 1983			Question #15(5)	DOD Safety Prog For Chem Sig/WARP	

Decontamination of Labs

QUESTION: Establish a system parallel to the one in the Chemical Surety Program which will require DOD to certify the decontamination of high risk labs which decide to leave the research program.

ANSWER: Unlike chemical agents, which are unique to the military, the agents and toxins studied in the biological defense research program are both readily available from a variety of commercial sources and are the subject of research supported by a number of private and non-defense, government organizations. When a contractor leaves the chemical defense program there is neither a requirement nor reason for that contractor to maintain stocks of government furnished chemical agents. In contrast, the organisms and toxins studied by contractors for the biological defense research program are, in virtually all instances, the established subject of study in that contractor's laboratory. Thus, in the absence of further DOD funding, biological defense research program contractors routinely continue research on the same organisms and toxins under support from their own organizations, other biomedical research funding organizations, industry, or private research foundations. That is, although the goals and objectives of the research projects will differ, the research material will remain the same. To decontaminate, and DOD to certify decontamination, of these laboratories would be viewed by the research community as an unnecessary and costly loss of valuable research capability and would likely restrict the availability to the DOD of some of this country's best biomedical scientists.

In the rare instance where a contractor is performing biological defense research program supported work with etiologic agents or toxins not otherwise studied in that laboratory, decontamination and certification would be incorporated into the routine safety office inspection of BL-3 and BL-4 laboratories. Decontamination of a BL-3 or BL-4 laboratory can be measured and documented in a fairly straightforward manner.

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United States Senate

COMMITTEE ON GOVERNMENTAL AFFAIRS

SUBCOMMITTEE ON
OVERSIGHT OF GOVERNMENT MANAGEMENT
WASHINGTON, DC 20510-8250

August 11, 1988

Dorothy Robinson, Esquire
 General Counsel
 Yale University
 451 College Street
 New Haven, Connecticut 06520

Dear Ms. Robinson:

We want to thank Yale University for participating in the Subcommittee hearing on July 27, 1988, concerning actions taken by the Department of Defense (DOD) to ensure that research related to chemical and biological warfare is conducted in a safe manner. The Subcommittee has several questions about Dr. Gregory Tignor's testimony and Yale's procedures to safeguard the high-risk research it conducts under its Biological Defense Program (BDP) contracts with DOD.

Please provide the following information by August 25, 1988.

1. Prior to the hearing, the Subcommittee requested copies of all reports of safety inspections conducted by Yale's biosafety officer since January 1, 1983, of laboratory facilities in which BDP research was being conducted. Records produced for Suite 600, Room 602, and Room 606 in the Laboratory of Epidemiology and Public Health (LEPH) indicate that inspections took place in 1983, 1984 and on June 24, 1988. There were no inspection records for 1985, 1986, 1987 and the first half of 1988. At the hearing, Dr. Tignor testified that no one at Yale had asked him whether he had inspection records for these years and that it was possible he did. Does Dr. Tignor have any additional inspection records? If so, please provide copies.

Dorothy Robinson, Esquire
August 11, 1988
Page Two

2. At the hearing, Dr. Tignor testified that he was uncertain whether Dr. John Frederico serves as the acting head of the Division of Occupational and Environmental Health Services, Yale's safety division. Is Dr. Frederico the acting head of the division? Is he filling that post on a part-time basis? Is it true that this post has not been filled on a full-time basis for more than one year?

3. At the hearing, Dr. Tignor testified that the inaccurate emergency telephone numbers printed on the cover of the Yale safety manual were corrected on a separate page that was inadvertently omitted from the manuals given to the Subcommittee and the General Accounting Office. Please provide a copy of that document, and indicate when it was first distributed and how it is currently distributed.

4. At the hearing, Dr. Tignor indicated that the meetings of the Yale Biosafety Advisory Committee were open to the public and that the minutes were or should be available for inspection. Later, he indicated that the meetings were open except when in executive session and was uncertain as to the availability of minutes.

(a) Please explain whether the meetings are open to the public, under what circumstances such meetings are closed to the public, and describe the precise standards used by the committee to call an "executive session." Please indicate whether the minutes are available to the public.

(b) Because the Subcommittee would like to review safety issues during the time that Yale's BDP contracts were being negotiated and performed, please provide complete copies of all committee minutes since January 1, 1985. These documents will be treated with appropriate confidentiality, including respect for the personal privacy of individuals and the relevance of the information to the subject of the Subcommittee's inquiry. If Yale has additional concerns about confidentiality, please describe the precautions that it would like the Subcommittee to observe.

Dorothy Robinson, Esquire
August 11, 1988
Page Three

5. Prior to the hearing, the Subcommittee requested copies of safety inspection records for the autoclave used in the animal facility on the eighth floor of LEPH, where BDP research is conducted. Does Yale have any autoclave inspection reports or descriptions of repairs made, other than the list of approximately 40 dates on which unspecified repairs were made to that autoclave? If so, please provide copies. If not, please explain why Yale does not retain such information in its files.

6. During the course of the Subcommittee's investigation and the hearing, serious questions were raised about Yale's biosafety oversight efforts. Among the issues raised were the extended vacancy in the top post of Yale's safety division, inadequate staffing in Yale's biosafety department, infrequent and poorly documented safety inspections of Yale's high-risk research facilities, poor recordkeeping, inadequate training and medical surveillance programs, inadequate consultation with custodial and maintenance personnel, possibly inadequate waste disposal practices and laboratory equipment, and confusion over the accessibility of the meetings and minutes of Yale's Biosafety Advisory Committee. What plans does Yale have to improve its safety oversight of high-risk BDP research?

Thank you for your assistance in this important matter. If you have any questions, please call Elise J. Bean at (202) 224-3682. Also, please find enclosed the October 1986 waste management study which was given to us prior to the hearing and which we are now returning to you.

Sincerely,



Carl Levin
Chairman



William S. Cohen
Ranking Minority Member

CL/WSC:ejb

Enclosure

Yale University

Office of the General Counsel
and Director of Federal Relations
P.O. Box 1074 Yale Station
New Haven, Connecticut 06520

Campus address:
451 College Street
Telephone:
203 432-4949

August 24, 1988

The Honorable Carl Levin
United States Senate
Chairman, Subcommittee on Oversight of
Government Management
Washington, D.C. 20510-6250

The Honorable William S. Cohen
United States Senate
Ranking Minority Member, Subcommittee
on Oversight of Government Management
Washington, D.C. 20510-5250

Dear Senator Levin and Senator Cohen:

This letter and the enclosed are submitted to the Subcommittee in response to the questions set forth in your letter dated August 11, 1988.

1. Other than those reports previously furnished to Subcommittee Staff, no inspection reports can be located by Yale's Biological Safety Officer for inspections of Dr. Tignor's laboratory space in Rooms 600, 602, and 606 LEPH. Dr. Tignor's files, which were searched by the Manager of Biological Safety at the time of the Subcommittee's request, have again been searched. Ms. Robyn Gershon, Yale's former Director of Biological Safety, has reported to me that she recalls having conducted inspections of Dr. Tignor's laboratory space during the period for which reports are missing from the files, and that those inspections did not disclose any significant safety problems.

2. Dr. John Federico is Acting Director of Yale's Division of Occupational and Environmental Health Services ("DOEHS"). (Dr. Federico previously served as Director of DOEHS from 1978 to 1983.) Dr. Federico has been temporarily relieved of his regular responsibilities as Medical Director of the Yale Health Plan to the extent necessary to permit him to effectively direct and oversee the DOEHS. The previous full-time Director of DOEHS left Yale's employ effective September 30, 1987, and the University is currently seeking a successor.

3. The emergency telephone numbers printed on the back cover of the Yale's Safety Manual for Biological Research Laboratories were accurate at the time the manual was initially prepared and distributed. When the University's internal telephone system was changed in October of 1986, all University telephone numbers were changed. At that time, DOEHS prepared self-stick labels showing the

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new telephone numbers, which could be affixed to the manuals over the printed numbers and posted in laboratories. One of these labels is enclosed. DOEHS distributed large quantities of the labels to departmental business managers, who in turn distributed them to laboratories. In addition, DOEHS staff have distributed more labels in the course of their routine visits to laboratories. A new telephone directory, listing the new numbers, was also published in connection with the change in the telephone system, and copies were distributed to every laboratory and office in 1986 and in each subsequent year. The campus police are also available 24 hours a day to respond to any emergency, and they are trained to contact DOEHS in the event of an emergency involving biological materials.

4. (a) Dr. Tignor's testimony was not clear regarding public attendance at meetings of the Biological Safety Committee and the public availability of minutes and we wish both to correct and to clarify the record on this issue. Yale's Biological Safety Committee (formerly the Biological Safety Advisory Committee) serves two functions: It serves as Yale's Institutional Biosafety Committee required under the NIH "Guidelines for Research Involving Recombinant DNA", and it also serves as an institutional oversight committee which reviews biosafety matters generally. When serving in the former capacity (e.g., reviewing investigator proposals for recombinant DNA research) meetings are normally open to the public, and minutes are made available to the public. To the extent the committee serves in the latter capacity, meetings are normally open to interested members of the Yale community (not the general public). Although non-committee members may be requested to leave (for example, if individual medical histories or sensitive administrative matters require discussion), no precise standards have been articulated for the calling of executive sessions. There is no policy or practice that minutes of these non-IBC meetings or portions of meetings are made available to the public.

(b) Copies of Biological Safety Committee minutes since January 1, 1985 are enclosed, with the understanding that the Subcommittee will treat them as confidential. In particular, we request that those portions of the minutes which do not directly pertain to BDP research (or the 6th, 7th and 8th floors of LEPH) not be copied or disseminated in any way.

5. Yale does not maintain separate records of inspections of the autoclave in the animal facility on the eight floor of LEPH. The functioning of the machine is monitored routinely each time it is operated, and Division of Animal Care personnel are trained to confirm that it reaches the proper temperature and pressure. (The temperature and pressure readings are recorded on time-temperature charts which are reviewed but not saved. A chemical indicator added to each load also confirms that the machine is reaching the correct temperature.) If the autoclave is not functioning properly, the Division contacts the Physical Plant Department and arranges for it to be serviced.

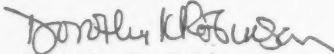
- 3 -

In addition, DOEHS monitors the functioning of the autoclave during inspections of the facility. If the DOEHS inspection of the facility does not reveal any problems with the autoclave, the monitoring is not mentioned in any inspection reports. Copies of DOEHS inspection reports of the eight floor animal facility previously have been provided to the Subcommittee.

6. The University has endeavored to respond to each of the specific questions which the Subcommittee has posed to it. We believe that the structure of Yale's biosafety oversight program is sound, that it has functioned well overall in maintaining a safe working environment for employees and that it includes multiple avenues -- strengthened particularly in the University's most recent collective bargaining agreements -- for consultation and communication between custodial and technical workers and faculty, supervisory staff and other management. The University is currently planning for the enhancement of employee safety training and communication on safety matters. In addition, DOEHS staffing currently is being reviewed in conjunction with the appointment of a successor Director of DOEHS. Those weaknesses which the Subcommittee has noted in practices on inspection documentation and on the articulation of policies on accessibility of committee meetings and minutes have been brought to the attention of the relevant University officials for their review. When that review is complete, appropriate action will be implemented.

I wish to reiterate that the University is firmly committed to the maintenance of safety throughout all of its activities, including but by no means limited to those undertaken as contract or for the Department of Defense in the program under the Subcommittee's review.

Sincerely yours,


Dorothy K. Robinson
General Counsel

001714

DIVISION OF OCCUPATIONAL AND
ENVIRONMENTAL HEALTH

DEPARTMENTS

* Biological Safety	43-20257
* Chemical Safety	43-20254
* Division of Occupational and Environmental Health	43-20259
* Employee Health	43-20255
* Environmental Health	43-20258
* Occupational Safety	43-20256
* Radiation Safety	43-23040

August 2, 1988

Senator Carl Levin
459 Russell Building
Washington, D.C. 20510

Dear Senator Levin:

As an employee of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), a principal preparer of the Draft Environmental Impact Statement on the DoD Biological Defense Research Program, and an attendee at the recent hearings of the Subcommittee on Oversight of Government Management on the issue of safety in the chemical and biological defense programs, I respectfully submit the following comments. I wish to state explicitly that these are my own personal observations, and that they in no way reflect official policies or positions of USAMRIID, the U.S. Army Medical Research and Development Command, the Department of the Army or the Department of Defense.

1) I was surprised to find that the Subcommittee has such broad and far-reaching powers to demand and receive information perceived to be of interest. The Subcommittee hearings have all the trappings of a judicial procedure, where witnesses present testimony and are questioned. However, this aura of judiciary quickly dissolves into an image of a kangaroo court when it becomes apparent that the witnesses must testify in the complete absence of their own advocate, and with no opportunity to pose questions of their own other witnesses.

2) As an observer, it appears that the Subcommittee accepts the testimonies of Dr. Levitt and Mr. Rifkin as articles of faith. I have not observed, or experienced in interviews with subcommittee staffers Jack Mitchell and Elise Bean, any inquiry whatsoever into the statements and allegations presented by these witnesses. Yet, particularly with respect to Dr. Levitt's testimony, additional information is readily available. For example, Dr. Levitt's allegations regarding the "missing" Chikungunya virus candidate vaccine and the "defective" FRL cell line were presented in the first amended complaint of Foundation on Economic Trends, et al v. Weinberger, et al, D.C.D.C. 86-2436. In the Offer of Judgement accepted by the Foundation on Economic Trends and the DoD, these claims were dismissed with prejudice. The results of the 1986 investigation into these same allegations, described by Colonel Huxsoll, were presented to Judge Richey and undoubtedly contributed valuable background information to the court's decisions. Additional information pertinent to many of Dr. Levitt's assertions exists in various USAMRIID records.

3) Mr. Rifkin has relied in large part on Dr. Levitt's unexamined statements regarding incidents, procedures and policies at USAMRIID and within the BDRP as a whole. However, he extrapolates far beyond even Dr. Levitt's presumed expertise, and alleges that "the potential escape of a hazardous organism from a BDRP laboratory poses a far more dangerous threat than even a nuclear meltdown." This assertion is patent idiocy. Although many of the isotopes released in nuclear mishaps (such as Chernobyl and Three Mile Island) are relatively short-lived and of immediate environmental and health concern (for example, isotopes of iodine), the substantive concern related to nuclear accidents is long-lived isotopes of uranium and its daughter decay elements, which can persist in the environment and potentially affect animal, plant and human welfare for centuries. The effects of these radioactive elements are direct: alpha, beta and gamma radiation do not require a reservoir for survival, nor do they require specifically susceptible hosts, nor optimal conditions for replication, nor complex transmission chains for dissemination of their effects. Radioactive isotopes cannot be rendered harmless by heat or chemical inactivation. In contrast, disease-causing organisms require all of these complex factors and more in order to cause effects in humans. In addition, although it is obvious that all of the ills of mankind have not yet been cured, organisms can be killed by relatively simple means.

It cannot be overemphasized that the organisms studied in the BDRP are not communicable diseases, that is, their primary mode of transmission is NOT from human to human. Given the organisms studied, the quantities of a given organism used, and the requirements of these organisms for survival, I believe that there is considerable scientific consensus that an accident involving a hazardous organism studied in the BDRP would not in any way be comparable to a serious nuclear accident.

4) Mr. Rifkin presented both oral and written testimony that drew on the Army Science Board "Final Report of the Ad Hoc Subgroup on the Army Biological Defense Research Program." He graciously pointed out in his oral testimony that the report carries a distribution limitation on its cover, "DoD and DoD contractors only." Were you aware that he had duplicated numerous copies of this report specifically for distribution to the press? I was told this by one of Mr. Rifkin's staffers, who was reluctant to give me a copy because she wanted to make sure there were enough for all the reporters present. Assuming that Mr. Rifkin had obtained his copy of the report through legitimate channels, such as the provisions of the Freedom of Information Act, this seems to me to be a flagrant violation of the spirit and intent of FOIA, as well as of the distribution limitation. Mr. Rifkin drew much attention to the

recommendations in the report regarding threat assessment and "Red Team" exercises. Has anyone thought to inquire whether the Army is considering implementation of any of these recommendations, or in fact whether any action on the report's recommendations is being considered?

5) Lastly, I would like to comment on the issue of perspective. This pertains to virtually all of the testimony and comments presented. For example, Dr. Levitt is but one former employee of USAMRIID. Approximately 500 people work at the Institute; why aren't more people lodging formal complaints about USAMRIID and the BDRP? The issues raised by Dr. Levitt have received wide publicity, especially in the local press, so the argument that everyone else is intimidated and fearful is a specious one. You read, for General Hildago's benefit, a list of safety violations at a chemical defense contractor's laboratory that were documented by a CRDEC inspection committee. Is the absence of a fire extinguisher at a designated location on a par with the improper disposal of hazardous chemicals? Surely an easily remedied practical deficiency such as a fire extinguisher belongs in a different realm of consideration from violations that have the potential to cause serious impact to human health and the environment. However, there was no obvious discrimination of these or any other issues into areas of importance, significance, or substantiveness.

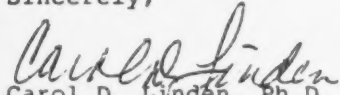
This lack of discrimination became most apparent in the interchange with Dr. Welch, where issues relating to OSHA-regulated safety concerns became confabulated with the specialized and unique considerations of laboratory bio- and chemical safety. OSHA and NIOSH regulations are generic, and intended for universal application throughout workplaces. Biological and chemical laboratory safety, however, depend in large part on the training and education of individuals performing work with such agents, as well as on combined considerations of the agent, procedures, equipment and facility. While consolidated regulation of laboratory safety may be perceived as desirable, this goal will not be well served by mixing the regulation of fire extinguisher positioning, etc. with the implementation of guidelines or regulations that specify the laboratory handling of biological and chemical agents.

In sum, the Subcommittee hearings left me with a great sense of disgust and disillusionment. In the absence of Senator Cohen, who, when he was present, pursued a rational and intelligent line of questioning, there was no pretense whatsoever of an intellectual pursuit of factual information. The report of the GAO, originally commissioned by the Subcommittee, was not even given the courtesy of an oral presentation. There was no effort to place the testimony of witnesses in perspective, nor to evaluate the actual track record of chemical and biological

defense laboratories outside of the presentation of examples of individual violations and problems.

I look forward to reading both the transcript of the hearings and the Final Report of the Subcommittee. I would like to remain optimistic that, removed from the enticements of the public eye, the subcommittee can arrive at reasoned and rational recommendations that are constructive for the Department of Defense, its contractors and the public.

Sincerely,



Carol D. Linden, Ph.D.
Program Analysis Officer
USAMRIID
Fort Detrick
Frederick, MD. 21701-5011

cc: Senator Cohen

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United States Senate

COMMITTEE ON
GOVERNMENTAL AFFAIRS

SUBCOMMITTEE ON
OVERSIGHT OF GOVERNMENT MANAGEMENT
WASHINGTON, DC 20510-4250

September 16, 1988

Carol D. Linden, Ph.D.
Program Analysis Officer
USAMRIID, Fort Detrick
Frederick, MD 21701-5011

Dear Dr. Linden:

Thank you for your letter discussing the Subcommittee's July hearings on Department of Defense (DOD) actions to ensure the safety of chemical and biological warfare (CBW) research.

Congress has broad authority, under the Constitution, to oversee actions taken by federal agencies. It can subpoena documents and witnesses from both the public and private sectors, and it can hold hearings for the presentation of testimony by and the examination of knowledgeable persons in the subject area. At hearings, witnesses have the right to have legal counsel present, and many do so. While witnesses do not have the right to cross-examine other hearing witnesses, the Subcommittee attempts, within the confines of time and logistics, for them to respond to each other's arguments and information.

The Subcommittee does extensive research before it holds a hearing and, afterwards, carefully evaluates the documents and testimony presented at the hearing. For example, the Subcommittee staff expended much effort to verify information Dr. Levitt provided the Subcommittee. The staff conducted interviews with USAMRIID employees, the Army Inspector General at Fort Detrick, the Fort Detrick Fire Department, and other individuals. It reviewed hundreds of pages of documents, including reports by the Army Inspector General, documents produced by the individuals involved in the events, Fort Detrick regulations, filings in the court case you identified, and other matters. The staff also reviewed information collected by Senator Mathias and Congresswoman Byron who had conducted inquiries of the events in question. It was only after this review that the Subcommittee concluded Dr. Levitt's allegations deserved to be aired in a public forum and allowed him to present his testimony.

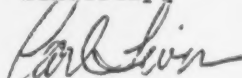
Your letter criticizes the distribution by one of the Subcommittee's witnesses, Jeremy Rifkin, of an Army Science Board report marked for "DoD and DoD contractors only." The action taken by Mr. Rifkin was his own and not in any way encouraged or supported by the Subcommittee. The Subcommittee is not in a position to control the actions of private parties.

Your letter expresses dismay at what you perceived to be a lack of perspective by the Subcommittee on CBW safety issues. It is possible that your perception of a lack of Subcommittee perspective on the complex safety issues associated with CBW research is the result of the swift pace of the hearings. Congressional hearings traditionally compress months of research into a few hours, a process which may cause observers to discern an uneven examination of the issues involved. In fact, the hearings you observed were preceeded and will be followed by agency and Congressional staff discussions that address both overall program objectives and specific issue concerns which are essential to meaningful policy development and effective implementation of policy goals.

Prior to the hearing, the Subcommittee publicly suggested a number of improvements in DOD's CBW safety programs which, at the hearing, DOD announced it had implemented or would implement in the near future. For example, the Subcommittee suggested, in a report dated May 11, 1988, that DOD create a central biosafety office for the Biological Defense Program (BDP), initiate an active safety oversight program for BDP contractors, and make certain NIH-CDC biosafety rules mandatory for BDP contractors. DOD announced at the hearing that it is in the process of implementing these suggestions and specifically thanked the Subcommittee for these and other suggestions.

We regret you feel that your experience with Congressional oversight of your program has been a negative one. Contrary to your fears, the Subcommittee has been and is still trying to play a constructive role in CBW safety matters. Judging by DOD's receptiveness to suggestions offered by the Subcommittee to date, the Subcommittee has succeeded in its goal of providing observations and ideas which will improve the safety of CBW research. We plan to continue our oversight efforts in this spirit.

Sincerely,



Carl Levin

CL:ejb

REPORTS

PRELIMINARY REPORT
OF THE MAJORITY STAFF OF THE
SENATE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
ON DOD'S SAFETY PROGRAMS FOR
CHEMICAL AND BIOLOGICAL WARFARE RESEARCH

May 11, 1988

In late 1986, at the direction of Senator Carl Levin (D-Mich.), chairman of the Senate Subcommittee on Oversight of Government Management (OGM Subcommittee), the OGM staff began a review of laboratories performing research for the Department of Defense (DOD) in the area of chemical and biological warfare (CBW). The purpose of the review was to examine the extent to which DOD is ensuring that CBW research is being conducted in a safe manner.

For 18 months, the OGM staff interviewed numerous persons knowledgeable in the CBW field, including DOD and other federal personnel, university scientists and private organizations. The staff reviewed thousands of pages of documents including annual and special CBW reports, CBW contracts, federal rules governing CBW research and the handling of hazardous materials, fire and safety codes, and accident reports.

Over the course of the investigation, the OGM staff uncovered serious deficiencies in DOD's management of safety issues in the CBW research program, including inadequate regulations, lax safety enforcement, and documented safety lapses. These deficiencies exist at the same time that the CBW research program is experiencing a period of rapid growth, with an increase in annual funding of more than 500% since 1980.

This preliminary report does not examine the current safety practices of particular facilities conducting CBW research. Nor does it reach final conclusions as to whether, currently, CBW research is being conducted in a safe manner. Rather, the report addresses DOD's management of safety issues -- what DOD knows and does about safety and the extent to which it exercises safety oversight in the CBW research program. The majority staff's preliminary conclusion is that DOD's management controls in the area of safety have serious failings. Among other problems, DOD appears to lack the necessary information and organizational apparatus even to evaluate the safety of a significant number of laboratories participating in the CBW research program.

In light of these deficiencies, the majority staff recommends that the OGM Subcommittee schedule hearings to examine what should be done to improve DOD's safety programs for CBW research.

Increasing Safety Risks

CBW research is an inherently dangerous proposition, and the risks are increasing.

The CBW research program plans and funds research related to both chemical warfare and biological warfare. The chemical warfare portion of the program funds the development of weapons and defensive measures. By treaty, the biological warfare portion of the program is restricted to developing defensive measures; the United States is not permitted to develop biological weapons. The biological portion of the program is thus known as the Biological Defense Program (BDP).

Chemical warfare (CW) involves the use of lethal or incapacitating chemical compounds for military purposes. The primary CW agents are blistering agents which destroy skin tissue and mucous membranes, blood agents which block or hinder the blood's ability to supply oxygen to the body, choking agents which attack the respiratory system, and nerve agents which attack the nervous system. Examples are mustard gas, hydrogen cyanide, phosgene and soman. Exposure to CW agents causes such incapacitating or lethal effects as blisters, burns, convulsions and asphyxia.

Biological warfare (BW) involves the use of living organisms for military purposes. BW agents include viruses, bacteria, fungi, rickettsia, and protozoans. Examples are Q fever, tularemia, rift valley fever, lassa fever, and eastern equine encephalitis. BW agents can cause either immediate or delayed symptoms, with incapacitating or lethal results, such as dizziness, shortness of breath, nausea, vomiting, fever, chills, blisters, convulsions, diarrhea and hemorrhaging.

A third category of CBW agents involves the military use of toxins. Toxins are poisonous chemical compounds derived from living organisms. Examples are snake venom, mycotoxin (poisons produced by fungi), scorpion toxin and marine toxins. These substances can be treated as CW or BW agents. Previously, toxins were not a significant element of CBW research due to the difficulty of obtaining sufficient research quantities. Now, new laboratory techniques permit the rapid, synthetic production of many toxins. Their effects on human beings are similar to those for BW agents.

The safety risks inherent in CBW research begin with the agents themselves. They are highly dangerous, involving many of the most deadly substances known. Hydrogen cyanide and certain snake venoms, for example, can kill a human being in minutes. Some BW agents, despite years of research, produce illnesses with no known cure. Even minute amounts of some CBW agents cause health hazards; in the case of many BW agents, the escape of even microorganisms must be prevented. If adequate safety precautions are not in place, a CBW agent can leak down an unprotected drain into ground water, blow through an unprotected ventilation shaft into the wind, escape on a laboratory worker's clothing, fly out with a wandering mosquito, or spill out of a container due to a shipping accident, natural disaster or terrorist attack. Once outside, some CBW agents, such as nerve agents and anthrax, can persist in the environment for years.

Second, the type of research being performed with CBW agents heightens safety concerns. In the CW area, for example, some research projects involve work with explosives. In both CW and BW experiments, the research may necessitate work with radioactive substances, unpredictable animals and clumsy safety equipment.

A third factor increasing safety concerns involves new biotechnology techniques which, for example, permit the mass production of CBW agents and the propagation of novel -- and even more deadly -- substances. In a May 1986 report to the House Appropriations Committee, DOD described the impact that these techniques have had on CBW research:

Perhaps the most significant event in the history of biological weapons development has been the advent of biotechnology. It enables the development of new microorganisms and products with new, unorthodox characteristics. Inserting BW related genetic traits into natural infectious microorganisms can potentially result in agents with greater virulence, antibiotic resistance, and environmental stability; and altered immuno protection and serological identification. . . . Bacteria and yeasts, genetically altered to produce . . . toxins . . . are miniature factories by virtue of their ability to proliferate rapidly. Large quantities of compounds, previously available only in minute amounts, thus become available at relatively low cost.

Report, Chapter 1, at 7-8. Due to the new techniques, DOD predicted the creation of BW agents which would "maximize infectivity and pathogenicity" as well as "environmental stability, persistency and potency"; BW agents which are immune to existing vaccines; and BW agents which attack the body through bioregulators that control perception, mood, organ function, body temperature and other body processes.

Id. at 8. DOD is charged with finding defenses to such agents.

The advent of genetic engineering and other techniques raise safety concerns that were not present in earlier CBW research efforts. They enable the overnight production of huge quantities of CBW agents and require work with even more deadly substances that may be able to live even more easily outside the laboratory. As these techniques and work with novel agents become more common in CBW research, DOD's safety programs need to keep pace.

In addition to dangerous substances, risky experiments and new technologies, still another factor has increased the risks of CBW research -- DOD's rapid expansion of the program.

In recent years, DOD spending on CBW research has increased dramatically. Annual reports published by DOD indicate that, during the years 1980 to 1986, annual CBW research funds have increased by more than 500%, from about \$63 million in 1980 to about \$348 million in 1986. (Spending on CW research has increased from about \$47 million to \$257 million; spending on BDP research has increased from about \$16 million to more than \$90 million.) See Exhibits A and B. From 1980 to 1986, DOD funds for CBW research have totalled more than \$1.5 billion.

The number of laboratories performing CBW research for the federal government has also increased dramatically. Documents in the possession of the OGM staff indicate that about 150 public and private laboratories are now involved in DOD-funded CBW research. These laboratories appear to be located in more than 30 states, the District of Columbia and 15 countries. They include prestigious universities, small biotechnology firms and large companies, in cities and suburbs throughout the United States.

The rapid increase in CBW funding and laboratories means that more CBW research involving more facilities is taking place in more locations throughout the country. It means there are not only more opportunities for accidents, but also that there is an increase in agent quantities and in the transport and handling of hazardous materials that the government should monitor. Further, the rapid pace of expansion means each CBW research project has to compete harder for the attention and limited resources of the DOD personnel charged with monitoring the research program.

The latest example of DOD's attempt to expand the CBW program is its proposal to build a Biological Aerosol Test Facility (BATF) at Dugway Proving Ground in Utah. The BATF is the first CBW facility designed for full-scale aerosol testing of BW agents. Aerosols of BW agents are particularly

dangerous, not only in terms of infecting laboratory workers, but also in terms of BW agents escaping the confines of a facility. The BATF has not yet been built due to objections by a number of organizations and individuals.

In sum, the dangerous nature of the CBW research program -- involving inherently dangerous agents and experiments, a rapidly expanding program, and the presence of CBW research projects throughout the United States -- indicates that a review of safety concerns is needed at this time.

Who Conducts CBW Research

DOD is the key federal agency responsible for CBW matters. Within DOD, the Army has been assigned lead responsibility for the CBW program, including research, procurement, training, policy development and budgeting. The Army plans and coordinates the CBW research program, doing much of the work itself, although it has delegated certain projects to other DOD components such as the Navy.

Within the Army, the lead component responsible for researching chemical weapons and CBW defensive measures (such as the Bigeye bomb, protective clothing, shelters, and detectors) is the Army Material Command (AMC). The lead component responsible for conducting CBW defensive medical research (such as developing vaccines for BW agents, antidotes for CW agents, and chemical and biological profiles of various substances) is the Army Medical Research and Development Command (MRDC).

Each of these two commands sponsors CBW research facilities. Within the AMC, the leader in CW research is the Chemical Research, Development and Engineering Center (CRDEC) at Aberdeen Proving Ground, Maryland. A second CBW facility is the Natick Research, Development and Engineering Center (NRDEC) at Natick, Massachusetts. Within MRDC, the leader in BW defensive medical research is the US Army Medical Research Institute for Infectious Diseases (USAMRIID) at Fort Detrick, Maryland, while the leader in CW medical research is the US Army Medical Research Institute for Chemical Defense (ICD) at Aberdeen Proving Ground.

All four of the DOD facilities, CRDEC, NRDEC, USAMRIID and ICD, possess a sizeable research complex, with multiple labs, storage facilities, administrative offices, shipping facilities, and numerous professional, clerical and other employees. They perform the bulk of DOD's in-house CBW research, although several other DOD laboratories also have CBW projects.

In addition to DOD's in-house research facilities, a significant amount of CBW research is performed by laboratories working under contract with DOD. In fact, since

1980, these contractors have increased their share of CBW research funds. In 1980, for example, the split between DOD and contractor facilities for CBW research funds was 60% to 40%, with federal laboratories getting the greater share. By 1986, that ratio has been reversed. See Exhibit C.

It is worth noting here that a number of non-DOD federal agencies also perform or oversee CBW research, usually using DOD funds. They include the Department of Commerce (its National Oceanic and Atmospheric Administration sponsors research on marine toxins which DOD funds), Department of Energy (performs several CBW research projects), Department of Health and Human Services (its Center for Disease Controls and Food and Drug Administration each perform CBW research projects), Department of Labor (its National Institute for Occupational Safety and Health helps research safe destruction of chemical munitions), Department of State (sponsors research to develop CBW detectors), National Aeronautic and Space Administration (sponsored a disease surveillance project), and Veterans Administration (several VA hospitals perform CBW medical research).

What Rules Govern CBW Research

The rules governing CBW research are lengthy, complex and interrelated. Here is a partial list:

Treaties -- There are two major CBW treaties which the United States has signed and ratified. The first treaty, drawn up in 1925, prohibits signatories from engaging in first use of CBW weapons during war, but contains no prohibition on research, development or possession of CBW weapons. The second treaty, drawn up in 1972, prohibits signatories from developing or possessing BW agents or weapons, but permits signatories to engage in BW research for protective purposes. It is due to these treaties that the United States possesses chemical weapons and sponsors chemical warfare research into both offensive and defensive measures, but possesses no biological weapons and restricts BW research to developing defensive measures.

50 USCS Chapter 32, CBW Program -- This is the key statute in the US Code which addresses CBW. It requires DOD to submit annual reports on CBW research, mandates safe disposal of CBW agents, restricts testing of CBW agents on civilian populations and in open air experiments, requires notice to Congress of experiments on humans, requires notice to other countries before delivering CBW agents or weapons, requires destruction of the obsolete chemical munitions stockpile and limits future chemical weapons to binary munitions.

Army Regulation 50-6, Chemical Surety Program -- This is the key regulation for DOD laboratories and contractors performing research with CW agents, called "chemical surety material" or CSM. It provides rules on safe laboratory practices, security requirements, emergencies, procedures for storage, transportation and disposal of CSM, and other matters. It also assigns oversight and safety responsibilities to particular DOD officials. This regulation does not apply to research involving only BW agents.

CDC-NIH rules on Biosafety in Microbiological and Biomedical Laboratories ["CDC-NIH Biosafety Rules"]; NIH Guidelines for Research Involving Recombinant DNA Molecules ["NIH Guidelines"] -- The CDC-NIH Biosafety Rules provide voluntary guidelines for laboratories performing research with infectious agents, including BW agents. Essentially, they establish four classes of experiments based upon the type of agents and research techniques to be used, and specify certain containment facilities and safety procedures for each class. (Class 4 experiments require maximum safety precautions.) Using essentially the same system, the NIH Guidelines classify experiments involving genetic engineering into one of the 4 categories, specify the safety precautions for each class, and mandate a biosafety committee in every laboratory to oversee its genetic engineering work. DOD has not made the CDC-NIH Biosafety Rules mandatory for CBW research, but does require all DOD research involving genetic engineering to comply with the NIH Guidelines. This requirement -- which affects about 10% of the BDP research contracts -- mandates safety precautions for those research projects. For the remaining 90% of BDP contracts -- projects which involve BW agents but no genetic engineering -- DOD apparently expects laboratories to follow the CDC-NIH Biosafety Rules, but no regulation requires them to do so.

Federal Acquisition Regulation (FAR) -- The FAR governs federal contracts. Some FAR rules have particular significance for CBW research contracts, including those on insurance and requirements to follow federal laws governing the transportation, handling and disposal of hazardous materials.

Standard Operating Procedures/Laboratory Safety Plans -- Most laboratories have a set of written procedures (sometimes called protocols) which are uniquely adapted to their facilities and address safe laboratory practices. Each of DOD's major CBW research facilities has such a set of rules. Each contractor working with CW agents is required, under the Chemical Surety Program, to submit to DOD for approval certain written

safety plans; however, contractors working with BW agents do not have a comparable requirement.

CBW Safety

The OGM staff was unable to locate a comprehensive safety program for CBW research, that is, a readily identifiable set of safety regulations and an office with overall safety responsibilities. Instead, the staff found two very different approaches to safety divided along chemical and biological lines.

Biological Defense Program. With respect to research involving BW agents, DOD's safety protections appear to be fragmented and, particularly for BDP contractors, completely inadequate. There is no comprehensive set of safety regulations for research with BW agents and toxins, no emphasis on safety in the contractor program, and no office that monitors contractor safety.

The lack of adequate safety regulations is particularly startling. The need for safety precautions is beyond dispute. As indicated earlier, BW agents are among the most deadly organisms known. And accidents do happen. The Army's leading BDP facility, USAMRIID, for example, has experienced fire in a high containment laboratory, misplaced vials of BW agents, laboratory spills and employee exposures to BW agents.

The CDC-NIH Biosafety Rules identified earlier establish a general framework for safe research with biological agents. Use of biosafety committees, four classifications of experiments, and differing levels of safety precautions for each class, have gained widespread acceptance among biological researchers. Among the safety precautions are requirements for laboratory containment facilities, rodent and insect control programs, special laboratory equipment, ventilation systems, warning signs and protective clothing; rules on restricting entry to work areas, taking showers, consuming food in the laboratory, storing biological agents, and destroying or decontaminating laboratory materials; systems to monitor the laboratory environment, the safety equipment and the employees' health; and procedures to prevent or respond to emergencies including vaccinations, quarantines, and medical treatment. While not conclusive on all aspects of safety applicable to research with BW agents and toxins, these rules go much of the way towards establishing a comprehensive safety scheme.

Despite their widespread acceptance, the CDC-NIH Biosafety Rules are not mandatory for either DOD laboratories or contractors performing research with BW agents and toxins. Nor has the BDP issued its own comprehensive safety rules governing research with BW agents and toxins.

Instead, the BDP treats safety in a piecemeal fashion, with scattered rules and incomplete regulations. For example, Army Regulation 70-65 requires each Army research facility using biological agents to establish its own safety rules. The regulation does not mention BW agents or toxins, nor does it contain requirements for coordinating, reviewing or updating the rules produced by each facility. USAMRIID is one example of an Army facility which has developed its own safety rules.

For BDP contractors, DOD appears to have imposed a safety rule across the board only for BDP contracts which involve genetic engineering. Such research must comply with the NIH Guidelines. But for the 90% of BDP contracts that do not involve genetic engineering, DOD imposes no mandatory safety rules, not even requirements that contractors establish their own safety programs, that they comply with recognized safety rules, or that they certify that they employ safe laboratory practices in connection with BW agents and toxins.

Examples of BDP research which do not involve genetic engineering and so appear to be outside any mandatory safety rules are experiments which define the characteristics of BW agents and toxins or which seek to identify unknown pathogens collected from CBW battlefields. In such cases, a contractor appears to be under no legal obligation to possess the proper containment facilities, to monitor its laboratory environment and workers, to report accidents to DOD, or to decontaminate its facilities when the research is complete.

In addition to the regulatory gap, the OGM staff has been unable to locate a safety office in the BDP program with the mission of ensuring safe laboratory practices by all facilities performing research with BW agents and toxins. The OGM staff did find that USAMRIID had its own safety office, consisting of a biosafety officer and two assistants. However, these persons are responsible only for monitoring USAMRIID's operations. While they are available for consultation by other facilities and, on occasion, have advised BDP contractors on biosafety issues, none are assigned the responsibility of monitoring the safety of off-site DOD and contractor laboratories.

The absence of BDP safety personnel means there appear to be no safety inspections of BDP contractors prior to contract awards. On occasion, MRDC or USAMRIID contracting personnel or scientists may conduct a pre-award, on-site visit to evaluate a BDP contractor's facilities. However, these visits apparently are not designed to be safety inspections; formal safety inspections do not appear to take place routinely; and the persons visiting the sites appear not to be safety specialists. There appears to be no

requirement that BDP contractors submit written safety plans for approval. After a contractor receives an award, there appears to be no requirement that BDP personnel conduct periodic safety inspections of the contractor's operations, and routine safety inspections do not appear to be performed. There are no safety reports required by DOD to be maintained for the contractors' laboratories. There is no BDP accident reporting system and no accident reports filed by BDP contractors. When a contractor leaves the BDP program, there appears to be no requirement that DOD certify decontamination of the contractor facilities. USAMRIID personnel indicate no BDP contractor has ever been terminated for unsafe practices.

In short, there appear to be no BDP personnel who are actively engaged in ensuring that BDP contractors employ safe laboratory practices. When combined with the poor regulatory scheme, the facts indicate there is simply no active safety program within DOD for contractors performing BDP research.

While it is possible that all laboratories performing research with BW agents and toxins are voluntarily employing safe practices, DOD cannot be sure of that or that such voluntary efforts are adequate, without exercising safety oversight. The key issues warranting further attention, then, are whether DOD should implement mandatory safety requirements for BDP research and, if so, what safety protections would be appropriate.

In 1987, a federal district court ordered DOD to prepare an Environmental Impact Statement (EIS) for the Biological Defense Program. Preparation of the EIS, due in May, is expected to have caused DOD to evaluate the overall safety of the BDP. The OGM staff was told that its preparation caused BDP personnel to conduct safety inspections of about a dozen laboratories. However, the extent to which the EIS addresses safety issues is not yet known, since it has not yet been publicly released. Distribution of that report should add to the Subcommittee's knowledge of BDP safety issues.

Chemical Surety Program. The approach to safety for research involving CW agents, while better than that for BDP research, also appears to have major shortcomings.

In contrast to the BDP, there is a comprehensive set of safety rules for research involving CW agents. The relevant regulation, identified previously, is the Chemical Surety Program, Army Regulation 50-6. It controls the possession, handling and disposal of chemical surety material (CSM). CSM is defined as "all lethal and incapacitating chemical agents that are either adopted or being considered for military use."

The Chemical Surety Program applies on its face to all in-house Army research facilities handling CSM. It also applies to all contractors handling CSM, through the Army's inclusion of extensive clauses in contracts where use of CSM is contemplated. Among the CSM safety rules which DOD laboratories and contractors must follow are: designation of a chemical safety officer and CSM custodian; written safety plans which, for contractors, must be approved by DOD; specified ventilation systems, protective clothing and emergency equipment; and specified procedures for transporting and storing CSM, keeping inventories and other records, monitoring personnel, equipment and the laboratory environment, performing experiments involving CSM, reporting accidents, and ensuring personnel and physical security.

Also in contrast to the BDP program, the OGM staff was able to locate two DOD offices responsible for monitoring safety in CW research. Staffed with safety and security specialists, one office is administered by the CRDEC, the other by ICD. The CRDEC safety office, with 26 employees, monitors CRDEC, several off-site government laboratories and about 15 contractors. The ICD safety office, called the Safety and Chemical Operations Office, is much smaller with 8 employees. It monitors ICD and about 38 off-site contractors.

The two offices perform several safety functions. They conduct on-site inspections of laboratory facilities prior to receipt of CSM, review and approve written safety plans, and conduct periodic safety inspections of laboratory facilities after receipt of CSM. For laboratories using undiluted CSM, the safety offices conduct annual accident drills, called a Chemical Accident/Incident Response exercise. Each inspection and accident drill is written up in a report maintained by the safety office that performed it. These reports include checklists identifying the items inspected and narrative descriptions of problems found. On occasion, follow-up inspections are performed at troubled sites. Finally, laboratories who decide to halt participation in CSM research must decontaminate their facilities and be certified as clean by the safety offices.

The OGM staff investigation indicates that the CW research program possesses the elements of a responsible safety program. There is an easily identifiable and detailed safety regulation, offices explicitly charged with enforcing safety, and evidence that these offices are actively engaged in enforcement efforts.

Unfortunately, despite these safety protections, the safety record for CSM research is far from comforting. For example, during 1986 and 1987, the Army's leading CW research facility, the CRDEC, was the subject of a massive probe which uncovered numerous safety problems there and throughout the

Aberdeen Proving Ground. The Army convened a formal board of investigation which conducted a year long study and filed 5 interim reports with more than 100 recommendations to correct deficiencies. When concluding its work in May 1987, the board indicated it had "identified a significant number of problems in the environmental, safety, and occupational health arenas," some of which would take years to correct. They included confusion over safety responsibilities, outdated and inadequate safety regulations, understaffed safety offices, an absence of safety inspections, inadequate training, and problems with storage and disposal of hazardous materials.

To illustrate the depth of the problem, here are some excerpts from the interim reports:

--"There are numerous structural deficiencies in some chemical laboratories, a number of which appear to be safety hazards. . . . [There is] a working laboratory with a gaping hole in the ceiling . . . [which has] existed for years."

--"Procedures for emergency medical response to chemical accidents, incidents or occurrences are not adequately established nor necessarily in line with the weight of expert medical opinion."

--"The facilities and present plans for the decontamination of chemical casualties are inadequate."

--"Insufficient attention is given to the inspection and maintenance of laboratories on the installation. . . . [T]he majority of the deficiencies are directly attributable to laboratory workers and their supervisors. In general, good laboratory practices are not being followed."

--During an inspection of the sanitary sewer system, "it was discovered that the system leg from Building E5100 had collapsed and the one from the Pilot Plant had numerous infiltration points."

--"Many laboratories are improperly using food-type refrigerators for the storage of chemicals . . . [which] constitutes a fire/explosive safety hazard."

--"Procedures for emergency communications in the Edgewood Area (EA) are inadequate. . . . Presently the EA phone switch is a mechanical relay type using technology that is about 20 years old. . . . [I]t often can take minutes to get a dial tone Laboratory personnel working with chemical agents . . . must have an absolutely reliable means of emergency communication."

--"The installation hazardous waste storage facility [HWSF] is unsuited for its current function and is in many ways inadequate. . . . [C]onditions . . . particularly in regard to personnel safety and hygiene, are deplorable. . . . There are no emergency decontamination facilities nor eye lavages . . . storage space for protective equipment . . . radio . . . [or] fire suppression system other than hand held extinguishers at each end of the HWSF buildings. . . . The training of HWSF personnel is inadequate."

The CRDEC is not the only CW research facility guilty of safety violations. Documents provided by the CRDEC and ICD safety offices indicate that a number of contractors, even those with long experience in CSM matters, have safety problems. Reports filed after safety inspections or accident drills repeatedly document contractor problems including, for example, an absence of required fire extinguishers, protective clothing, medical kits, decontamination solutions, employee training, and annual physical examinations; outdated safety plans; incomplete or missing safety inspection records; "extremely dirty" laboratory facilities; problems with emergency showers and eye washes; improper waste disposal practices; and storage problems. Poor performance by contractor employees during accident drills appears common. On at least five occasions, the Army has terminated contractors for failure to comply with the CSM rules.

The reasons for such safety violations and what can be done about them are pressing issues that warrant further examination by the OGM Subcommittee.

There are other problems with the CW safety program as well. For example, the periodic safety inspections of CW contractors are not always performed on a timely basis, especially by the ICD office. One extreme example is an ICD contractor which appears not to have been inspected in 4 years. A related problem is that actions taken by the offices to follow-up on safety violations are poorly documented. In many cases, it is difficult to determine whether the contractor remedied deficiencies cited in a particular report.

A third area of concern has to do with the CSM rules. While detailed in many areas, the CSM rules appear to have several safety gaps. For example, there appear to be no rules dealing with the issue of toxins and whether these substances constitute CSM. There are no rules requiring laboratories handling CSM to notify local officials, such as local fire marshalls, of the presence of CW agents in the community and of special fire-fighting needs that the laboratory may have. There are no rules about notifying neighbors and local communities of CBW facilities in their

midst. There appear to be no rules requiring the Army to perform a risk assessment of each new laboratory asking to handle CSM, in which the Army evaluates the laboratory's physical location -- its proximity to homes, schools and other community facilities -- in deciding whether CW research ought to be conducted at that site. There appear to be no rules requiring plans for evacuating surrounding communities in cases of emergency. These and possibly other deficiencies in the CSM rules merit a careful review.

In sum, while the safety protections for research involving CW agents are better than those for research involving BW agents, Congress should not rest easy. Attention needs to be paid to such issues as poor compliance with CSM safety rules, irregular safety inspections, and safety gaps in the CSM regulations. These and other safety problems in the CW research program need to be addressed.

Conclusion

The OGM staff recommends that hearings be held to examine the issues raised in this preliminary report, as well as issues that may be raised by the Environmental Impact Statement on the Biological Defense Program. Among the issues that merit review are:

- (1) whether DOD should issue comprehensive safety regulations for research involving biological warfare agents and toxins and, if so, the substance of such regulations;
- (2) whether DOD should create an office within the Biological Defense Program to monitor DOD laboratories and contractors for safe practices involving biological warfare agents and toxins;
- (3) how to compel laboratories performing research with chemical warfare agents to improve the safety of their operations; and
- (4) what improvements need to be made to the Chemical Surety Program and the safety offices monitoring laboratories that perform research with chemical warfare agents.

EXHIBIT A

FEDERAL FUNDING OF
CHEMICAL AND BIOLOGICAL WARFARE RESEARCH

FISCAL YEAR	CHEMICAL WARFARE R&D	BIOLOGICAL WARFARE R&D	TOTAL ANNUAL CBW R&D
FY 80	\$ 47,565,000	\$ 16,026,000	\$ 63,591,000
FY 81	101,048,000	15,096,000	116,144,000
FY 82	167,812,000	21,554,000	189,366,000
FY 83	163,371,000	38,802,000	202,173,000
FY 84	258,751,000	62,500,000	321,251,000
FY 85	285,977,000	68,528,000	354,505,000
FY 86	257,553,000	90,626,000	348,179,000
TOTAL:	\$1,282,077,000	\$ 313,132,000	\$ 1,595,209,000

Prepared by Senate OGM Subcommittee Staff, May 1988. Funding amounts are taken from the Department of Defense Annual Reports on Chemical Warfare and Biological Defense Research Program Obligations, FY80-FY86. The figures indicate funding for research and development efforts and do not include funding for other types of CBW procurements, such as the purchase of weapons systems, defensive equipment or other items.

Figures do not include funding amounts for the Ordnance Program which has supported research of smoke, flame, incendiary, herbicide and riot control agents, and support equipment.

EXHIBIT B

FEDERAL FUNDING OF CHEMICAL AND BIOLOGICAL WARFARE RESEARCH, 1980-1986

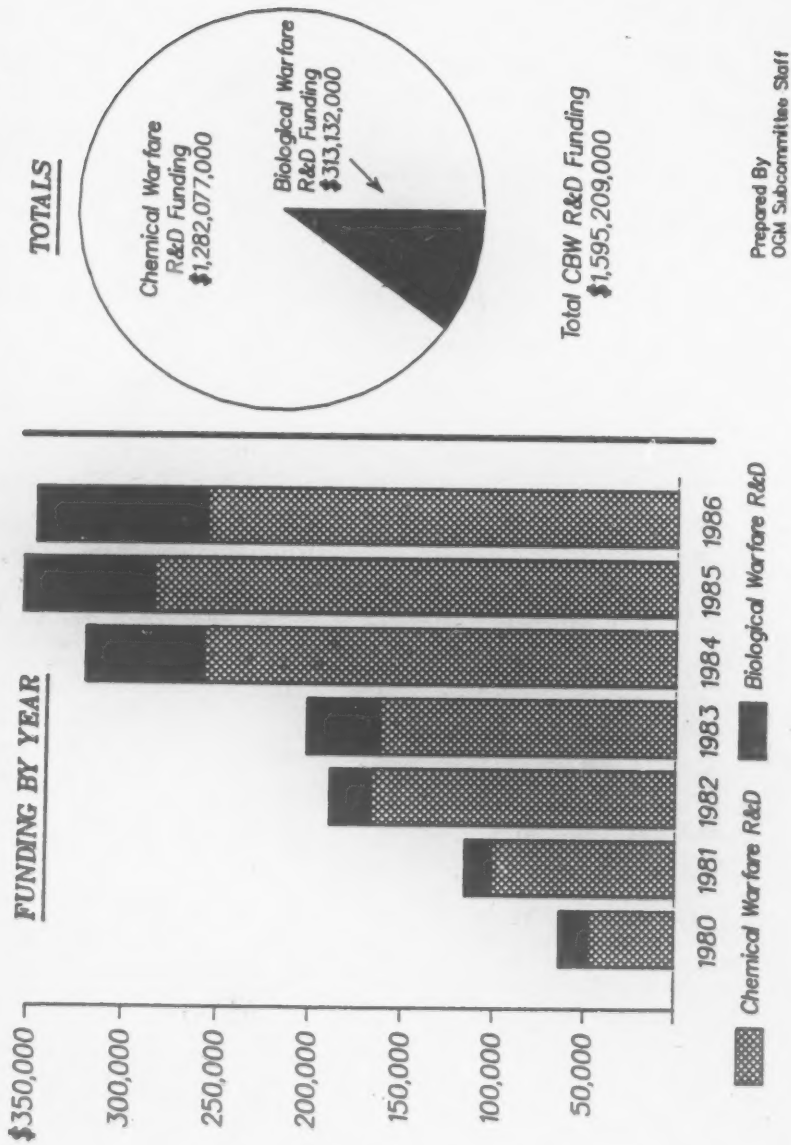


EXHIBIT C

IN-HOUSE V. CONTRACTOR SPENDING FOR
CHEMICAL AND BIOLOGICAL WARFARE RESEARCH

	FUNDS FOR IN-HOUSE R&D	FUNDS FOR CONTRACTOR R&D	TOTAL ANNUAL CBW R&D	PERCENT ALLOCATED TO CONTRACTORS
FY 80	\$ 37,310,000	\$ 26,281,000	\$ 63,591,000	41%
FY 81	61,232,000	54,912,000	116,144,000	47%
FY 82	82,104,000	107,262,000	189,366,000	57%
FY 83	82,102,000*	120,071,000*	202,173,000	59%
FY 84	115,300,000#	205,951,000#	321,251,000	64%
FY 85	120,128,000+	234,377,000+	354,505,000	66%
FY 86	130,591,000	217,588,000	348,179,000	62%
TOTAL:	\$628,767,000	\$966,442,000	\$1,595,209,000	61%

Prepared by Senate OGM Subcommittee Staff, May 1988. Figures derived from Department of Defense Annual Reports on Chemical Warfare and Biological Defense Research Program Obligations, FY80-FY86. "In-House R&D" refers to CBW funds allocated to federal research facilities; "Contractor R&D" refers to CBW funds allocated by contract. The figures indicate funding for research and development efforts and do not include funding for other types of CBW procurements, such as the purchase of weapons systems, defensive equipment or other items. The figures do not include funding for the Ordnance Program which has supported research of smoke, flame, incendiary, herbicide and riot control agents, and support equipment.

* Includes \$138,000 in Navy chemical warfare research funds which the FY83 Annual Report fails to designate as either in-house or contract funds. These funds have been allocated between the two categories using the ratio of in-house/contract spending for other Navy chemical warfare research funds during FY83; \$81,000 is designated as in-house funds and \$57,000 as contract funds.

Includes \$1,401,000 in Air Force chemical warfare research funds which the FY84 Annual Report fails to designate as either in-house or contract funds. These funds have been allocated between the two categories using the ratio of in-house/contract spending for other Air Force chemical warfare research funds during FY84; \$96,000 is designated as in-house funds and \$1,305,000 as contract funds.

+ Includes \$11,093,000 in Air Force chemical warfare research funds which the FY85 Annual Report fails to designate as either in-house or contract funds. These funds have been allocated between the two categories using the ratio of in-house/contract spending for other Air Force chemical warfare research funds during FY85; \$937,000 is designated as in-house funds and \$10,156,000 as contract funds.

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DEPARTMENT OF THE ARMY
OFFICE OF THE CHIEF OF STAFF
WASHINGTON D C 20310-0200

27 Jun 88

MEMORANDUM FOR: DIRECTOR OF THE ARMY STAFF

SUBJECT: Chemical Management Evaluation of Chemical Safety

1. The Office of The Inspector General recently concluded its management evaluation of the Army's Chemical Safety Program.
2. I have reviewed and approved The Inspector General's recommendations in the enclosed report. Although many positive areas were identified, there are areas where improvement is needed.
3. Request you review The Inspector General's recommendations for action and provide me a copy of your implementing action plan within thirty days.

Encl


ARTHUR E. BROWN, JR.
General, United States Army
Vice Chief of Staff

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CHEMICAL MANAGEMENT
EVALUATION

CHEMICAL SAFETY

TECHNICAL INSPECTIONS DIVISION
DAIG

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RECOMMENDATIONS

1. The Director for Army Safety:

- a. Expedite the publication of AR 385-61 (Draft), Chemical Safety.
- b. Expedite the hire of a safety professional with chemical experience and expertise for the Army Safety Office.
- c. Emphasize chemical safety program oversight.
- d. Collect, analyze, and disseminate chemical safety information throughout the Army.
- e. Simplify the definitions and reporting requirements for chemical mishaps.
- f. Support PEO/PM Chemical Demilitarization in meeting requirements for safety professionals in support of the demilitarization program.

2. Commanders of AMC, USAREUR, WESTCOM, TRADOC, and MRDC:

- a. Ensure that annual safety program evaluations are conducted and that they include chemical safety.
- b. Evaluate adequacy of staffing for chemical safety at all levels.

3. PEO/PM Chemical Delimitarization identify requirements for safety professionals to support demilitarization.

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SECTION I

GENERAL

INTRODUCTION. A Chemical Management Evaluation (CME) is defined in AR 20-1 as "an evaluation to determine adequacy of support and technical and command guidance, and to identify management, systemic, or functional problem areas in the Army chemical surety program. . ." The CME expands the focus beyond the compliance methodology associated with chemical surety inspections (CSI) by looking at command levels at and above unit/activity level Army wide. The purpose of the CME is to provide a systemic look at the Army's chemical program to uncover problems and recommend solutions as well as note praiseworthy areas.

Technical Inspections Division, Department of the Army Inspector General Agency, conducted a CME of the Army chemical safety program during the period January to April 1988. Impetus for the evaluation was the results of CSI, Army Materiel Command (AMC) surety inspections, recent chemical mishaps, input from the Army staff and the field, and from in-house assessment of the Army chemical mission. The results of this evaluation take on increased significance in light of the Congressional mandate for the demilitarization of most of the existing chemical stockpile. While this evaluation focused on the present Army chemical safety program as it pertains to the storage of the existing stockpile, the results also provide insights useful for structuring the safety program for the demilitarization period. The evaluation examined the structure of chemical safety in terms of organization and function, the pronency and content of chemical safety policy, chemical safety training for operators and professional safety personnel, oversight and evaluation of the chemical safety program, and the reporting of chemical mishaps. The CME was conducted to identify strengths and weaknesses in chemical safety, to identify root causes of problems, and to recommend practical fixes.

BACKGROUND. The current unitary chemical stockpile is stored at eight CONUS locations, Johnston Island in the Pacific, and in Europe (See Figure 1). The vast majority of the stockpile is the responsibility of the Army Materiel Command. The U.S. Army Training and Doctrine Command (TRADOC) is also a player in the chemical safety arena with the Chemical Decontamination Training

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Facility at Fort McClellan, Alabama, as is Medical Research and Development Command with the Medical Research Institute for Chemical Defense at Aberdeen Proving Ground, Maryland. The stockpile is basically static and subject only to ammunition surveillance sampling and inspection, routine maintenance, and limited scale demilitarization operations. These activities routinely place a number of personnel in close proximity to chemical agents. Demilitarization of the unitary stockpile will require extensive handling and movement of the stocks with a corresponding increase in risk of an accident or incident.

The Army chemical safety program, within the Army Safety Program, consists of policy formulation, development of procedures based on sound policy, training and execution of those procedures, oversight from local through DOD level to provide data for investigation and analysis, and refinement of policy and procedures (See figure 2). The objectives of the Army Safety Program are prevention of injury and occupational illness, damage control, accident prevention, compliance with statutory and regulatory requirements, liability limitation, and occupational health. Accomplishment of these objectives achieve the goals of minimizing accidental manpower and monetary losses and providing a safe and healthful environment at all times for Army personnel and others exposed to Army operations.

Chemical safety issues can be highly sensitive, charged with emotion, and of great public interest. The chemical stockpile and its planned demilitarization have been subject to speculation and general misunderstanding within the past few years. It is critically essential that the Army demonstrate a credible, operational safety program in place to assure the public and elected officials that the chemical stockpile is being managed responsibly.

OBJECTIVES. The objectives of the CME were to:

- Determine the adequacy of chemical safety policies and procedures.

- Assess the effectiveness of the Army Chemical Safety Program in terms of organization and function.

- Assess the adequacy of chemical safety training programs.

- Assess the adequacy of chemical safety oversight, reporting, and analysis.

METHODOLOGY. The DAIG charter for the conduct of chemical management evaluations is contained in AR 20-1 and AR 50-6. The stated goal of this CME was to assess the adequacy of the

chemical safety program. As used in this evaluation and throughout this report, the term chemical refers to toxic chemical agents and munitions as defined in AR 59-6. The evaluation was designed to be an issue-oriented, systemic evaluation based on a review of regulatory guidance, doctrine, plans, policies, procedures, and resources. Information was collected through review of documentation and by personal interviews with key personnel. All levels concerned with chemical safety were covered, from HQDA to toxic handlers at storage locations. No checklists were used and no ratings were assigned. Observations related to local problems were left with local commanders for disposition. Significant observations were recorded as findings and verified by appropriate commands and agencies. Routine information and results of interviews were recorded on memoranda for record (MFR). In-process reviews were held at several points during the evaluation and at the end to ensure thorough coverage of the issues.

SCOPE. The evaluation included HQDA, all four of the MACOM involved with chemical safety (USAREUR, WESTCOM, TRADOC, and AMC), and a sampling of installations within each MACOM. Pre-inspection visits and briefings were conducted at HQDA and the AMC Field Safety Activity, Charlestown, IN. Evaluation visits were conducted in phases with an IPR between phases. The first phase consisted of HQDA, ODSCOPS, the Army Safety Office, the US Army Nuclear and Chemical Agency, and the Army Safety Center. The second phase included HQ, AMC, Pine Bluff Arsenal, Tooele Army Depot, and Aberdeen Proving Ground (Edgewood Area). The third phase included HQ, WESTCOM, Johnston Island, HQ, TRADOC, Redstone Arsenal, Fort McClellan, Lexington-Bluegrass Army Depot, USAREUR, HQ, AMCCOM, and the AMC Field Safety Activity. Figure 3 shows the locations visited and gives the composition of the evaluation team. (NOTE: Throughout this report, for OPSEC purposes, no more specific description than USAREUR is given for any overseas locations visited other than Johnston Island.)

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SECTION II

EVALUATION RESULTS

GENERAL. Evaluation objectives were accomplished. The evaluation identified strengths as well as systemic problems which adversely impact on chemical safety.

1. **POLICY.** The Director for Army Safety, dual hatted as the Commander, USASC, is the policy proponent for chemical safety in accordance with AR 385-10. As such his mission includes:

"Develop and recommend Army Safety Program (ASP) doctrine, policies, procedures, standards, practices, and plans. . . manage specific ASP functions to include: OSHA and ammunition and explosives. . . ."

The Army Safety Office and Army Safety Center representatives interviewed clearly viewed chemical safety as an element of explosives safety and within their sphere of responsibility. There is currently no policy document at the Army level on chemical safety. AR 385-61, Chemical Safety, in draft for over two years has been rejuvenated and is currently being coordinated with ARSTAF and MACOM. In addition, a position in the Army Safety Office has been approved for a safety specialist with chemical expertise as a specific job qualification.

The evaluation revealed that DA level chemical safety mission execution suffers from a lack of published policy guidance, inadequate staffing, no systematic program of oversight, and a less than clear statement of chemical safety responsibilities. As a result, the USASC, focal point for other Army safety matters, is not recognized by the field as having any chemical safety responsibilities or expertise. The USASC has not played an active role in any chemical safety issues other than participating in the 1987 investigation of a chemical incident at Johnston Island. The chemical safety role of the newly formed Technical Center for Explosive Safety is not yet clearly defined. The void in chemical safety proponentcy at the DA level has resulted in MACOM developing their own policies independent of any central direction or control. AMC has become the de facto proponent of chemical safety and has filled the policy void with AMCR 385-131. The other MACOM and their chemical activities have adopted or adapted, in varying degree, the AMC regulation to suit

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their purposes. The AMC regulation provides comprehensive, sensible guidance for depot-type operations, but is not wholly applicable to the TRADOC, WESTCOM, USAREUR, or Medical Research and Development Command (MRDC) chemical missions.

The Army's chemical safety expertise resides at the Chemical Safety Office, AMC Field Safety Activity, Charlestown, Indiana. They provide advice and assistance on day-to-day operations to all MACOM. MACOM other than AMC, as well as their chemical activities, call on FSA freely, and assistance is readily provided. This is usually done on an informal basis, leaving implementation of FSA advice to the discretion of the MACOM or installation seeking help. The depth and breadth of experience at FSA almost always provides answers to MACOM queries; however, the guidance is not binding, and there is no honest broker examining the advice or the implementation.

2. ORGANIZATION AND FUNCTIONS. The evaluation took an across the board look at the chemical safety population (GS-018 and GS-803) from Department of the Army level down through installation. Clearly evident was the lack of depth in the number of trained chemical safety professionals, with expertise only "one deep" in most instances. This situation is compounded when safety personnel are also responsible for other general safety areas.

The evaluation team found the lack of chemical safety policy at DA level was directly attributable to lack of staffing. The Army Safety Office is one deep in chemical expertise, and his duties are myriad, so there has been little time to develop and publish chemical safety policy. The lack of staffing also limits opportunity to visit the field. "One-deepness" in chemical safety expertise permeates the entire community, strapping the safety professionals to their desks and leaving little time for the oversight function.

The team found that at some installations, the chemical safety experts had difficulty doing required inspections and surveys of all agent operations and areas. For example, at one installation whose sole mission is chemical, two vacancies in the safety office have resulted in no safety inspections being conducted because the remaining safety specialist's time is fully taken with laboratory hood certifications and preoperational surveys. At another installation the team found that administrative requirements such as site safety submissions, reduce the safety specialists time to the point they were seldom seeing surveillance or storage operations.

The lack of depth in chemical expertise coupled with other non-related safety responsibilities has a direct impact on the lack of viable oversight of chemical safety. The overall qualification and dedication of the chemical safety professionals

currently in the field is outstanding. However, a significant increase in the number of safety professionals with expertise in chemical agent safety, and the establishment of a central management agent for training chemical safety professionals is essential for the Army to fill its immediate and long term requirements. The heightened awareness by the public and the possible risk of liability to the Army stemming from current chemical stockpiles will increase dramatically once demilitarization becomes operational. The present system which does not adequately support current requirements, cannot hope to provide the future number of chemically qualified safety professionals required.

3. TRAINING. The evaluation examined two aspects of chemical safety training. First, the chemical training provided to safety professionals in the GS-603 and GS-018 career fields was examined. The evaluation also examined the chemical safety training of toxic chemical workers.

Safety professionals are developed through intern programs at the USASC and through AMC's independent internship programs. The internship programs all include one week of chemical safety training at the Field Safety Activity. Chemical expertise is really developed at AMC chemical depots during the intern's OJT program. With one exception, all the personnel interviewed who were involved in chemical safety had come through the AMC programs and all had extensive chemical experience. The evaluation disclosed that chemical safety training for safety professionals is adequate, and some truly outstanding individual intern development programs are in effect at the installation level.

Each chemical activity evaluated had a formal training program for toxic workers. The large majority of these workers are civilians who undergo a formal certification process as part of their job qualification training. Military chemical agent workers undergo less formal on the job training comparable to their civilian counterparts. In every case, the program included initial and sustainment training. Safety was a dominant theme in all training and safety professionals played an active role by reviewing POI, monitoring instruction, and in some cases conducting training. Workers generally felt their training was objective, sufficient, and emphasized safety.

4. OVERSIGHT, REPORTING, AND ANALYSIS.

a. OVERSIGHT/INDEPENDENT ASSESSMENT. Oversight of the Chemical safety program is not effectively implemented at all levels from HQDA to installation.

AR 385-10 requires that HQDA (OTIG) conduct periodic evaluations of MACOM safety programs. MACOM commanders, in turn, are

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required to do likewise for their subordinates on an annual basis. MACOM safety directives further implement this requirement for their MSC/installations.

AR 385-18 includes a checklist for the annual evaluation. Conducted properly, and all-inclusively, it provides a programmatic, systemic look at the command level being evaluated.

Other evaluations which provide oversight of chemical safety are conducted by the DOD Explosive Safety Board (DEESB), the DAIG Chemical Surety Inspections, the USAREUR IG Surety Inspections, and the AMC Surety and Operational Inspections. The DEESB survey ensures compliance of conventional ammunition (including chemical) operations with site safety submissions and with DOD 6055.9-STD. The surety inspections address chemical safety as it pertains to the overall surety program.

The evaluation revealed that there is not an effective oversight program in place for chemical safety; that chemical safety has slipped through a crack between the overall safety program evaluation and the chemical surety inspections.

The safety program evaluations required by AR 385-18 and MACOM supplements thereto generally do not address chemical safety, but consider it to be adequately addressed by surety inspections. However, safety is only one of several functional areas examined by the Chemical Surety Inspection (CSI). Since the CSI is essentially a compliance inspection using sampling techniques, chemical safety does not receive a comprehensive systemic or programmatic examination.

The primary impact of ineffective oversight is increased risk. Effective oversight of the safety program ensures that approved procedures are followed at the operator level. Secondly, effective oversight provides assurance to the Army leadership that a viable safety program is in place. Effective oversight also identifies systemic problems in a timely manner so that they can be addressed before they become incident statistics. Finally, an effective oversight program provides the Army a stronger, more credible position from which to deal with the public on this emotional issue.

b. CHEMICAL MISHAP REPORTING. The reporting system for chemical mishaps is encumbered with confusing definitions, overly stringent and duplicative reporting requirements, and excessive intervention from all levels as the report works its way through channels.

The regulatory reporting requirements for chemical mishaps are published in AR 50-6. The guidance contained in AR 50-6 has been amplified by DA message to cover reporting of minor leaks and occurrences.

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The evaluation revealed great confusion in the field as to what to report. Generally, when a mishap occurs, reporting begins with a telephone consultation between the installation and the next higher headquarters to determine whether the mishap is a "minor leak", "occurrence", "incident", or "accident" with each term subject to question at each level of command to HQDA. Even minor mishaps or discovered leakers, with no release of agent outside the confines of areas where all personnel are fully protected are reportable to HQDA within 3 hours.

Another factor in the reporting system is the very effective "informal organization" within the chemical community. This "informal organization" is of great value in solving technical and operational problems on a daily basis, but it often causes problems in the wake of a chemical mishap. Individuals at MACOM or DA level are often informed of the mishap before the official reporting system gets to the proper operational element at the corresponding level. This usually results in added confusion and superfluous requirements levied on personnel on the ground who are responsible for working the problem.

c. **COLLECTION AND ANALYSIS OF CHEMICAL SAFETY DATA.** There is no central agency within the Army with the responsibility for collection, analysis, and dissemination of chemical safety information.

The evaluation revealed that there is no formalized system for collecting, analyzing or disseminating information on chemical safety. The AMC Field Safety Activity, Charlestown, IN, has voluntarily taken on this responsibility for AMC, and provides safety data to AMC subordinates and provides the data informally to USAREUR, WESTCOM, and TRADOC elements.

Accident analysis is not conducted by the USASC for chemical accidents/incidents.

The impact of this shortcoming is that there is no established means of disseminating lessons learned from incidents or sharing good ideas throughout the chemical community.

SECTION III

CONCLUSION AND RECOMMENDATIONS

CONCLUSION. The evaluation clearly revealed that at the most critical point, where workers are in close proximity to agent, the chemical safety program is the strongest. The workers at chemical storage areas are confident that they work in a safe environment. Their SOP reflect safe practices, and their supervisors are safety conscious. The weaknesses identified by the evaluation are those which place the Army and its leadership at increased risk in an arena with high public interest, extensive media coverage, and close congressional scrutiny. Correction of these weaknesses will provide the Army a stronger, more credible position from which to approach the demilitarization of the unitary stockpile, as well as the continued safe storage of the stocks until demil is completed. Aggressive pursuit of a strong safety program with effective policies, oversight to ensure implementation, and analysis to ensure refinement and continuous improvement ensures that the goals of the Army Safety Program are met in the chemical safety arena.

RECOMMENDATIONS:

1. The Director for Army Safety -

- a. Expedite the publication of AR 385-61 (Draft), Chemical Safety.
- b. Expedite the hire of a safety professional with chemical experience and expertise for the Army Safety Office.
- c. Emphasize chemical safety program oversight.
- d. Collect, analyze, and disseminate chemical safety information throughout the Army.
- e. Simplify the definitions and reporting requirements for chemical mishaps.
- f. Support PEO/PM Chemical Demilitarization in meeting requirements for safety professionals in support of the demilitarization program.

"This document contains information
EXEMPT FROM MANDATORY DISCLOSURE under
the FOIA. Exemption 5 Applies."

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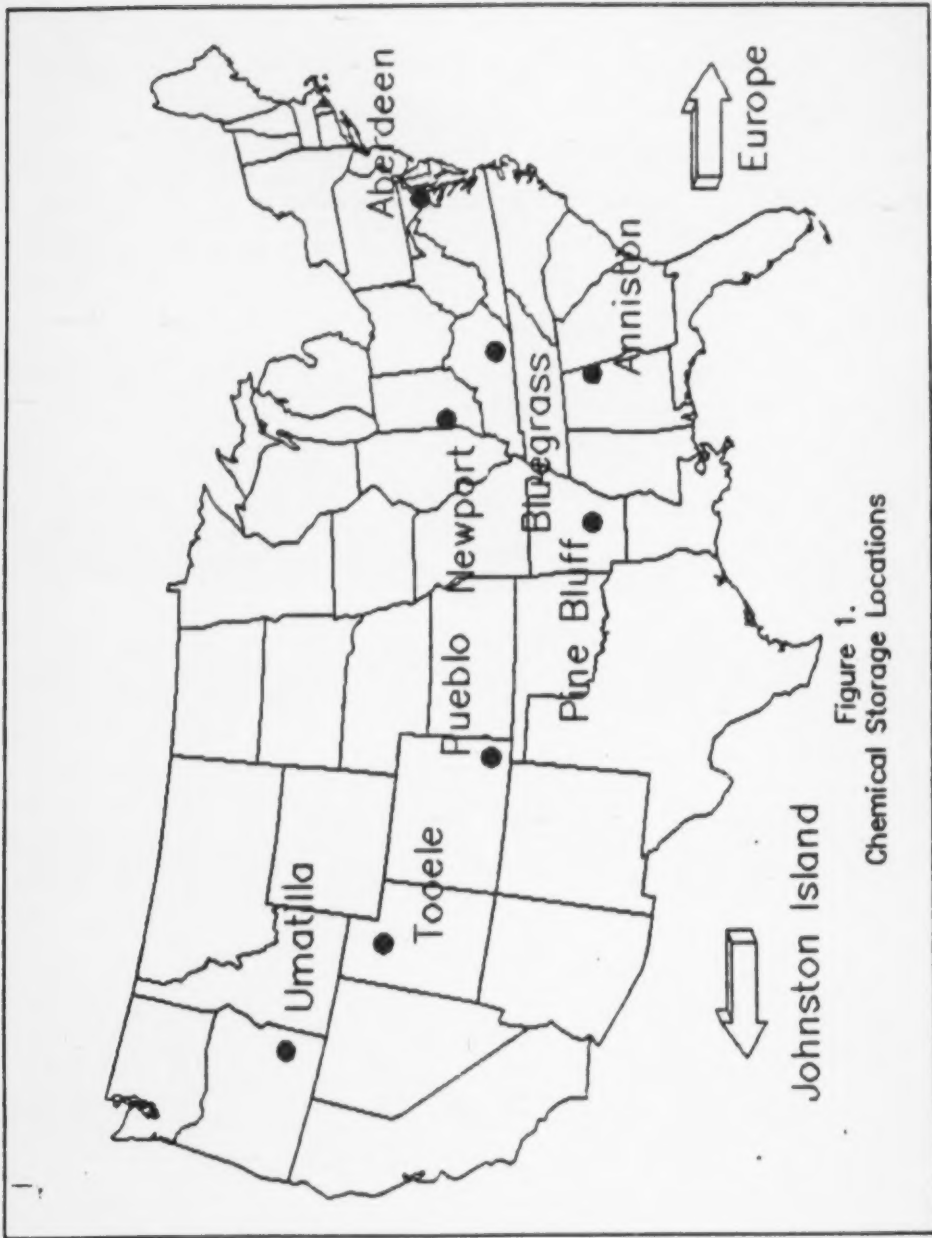
2. Commanders of AMC, USAREUR, WESTCOM, TRADOC, and MRDC:

- a. Ensure that annual safety program evaluations are conducted and that they include chemical safety.
- b. Evaluate adequacy of staffing for chemical safety at all levels.

3. PEO/PM Chemical Demilitarization identify requirements for safety professionals to support demilitarization.

REFERENCES

DOD 6055.9-STD	DOD Ammunition and Explosive Safety Standards
AR 385-10	The Army Safety Program
AR 50-6	The Chemical Surety Program
AR 385-40	Accident Reporting and Records
AR 385-64	Ammunition and Explosive Safety Standards



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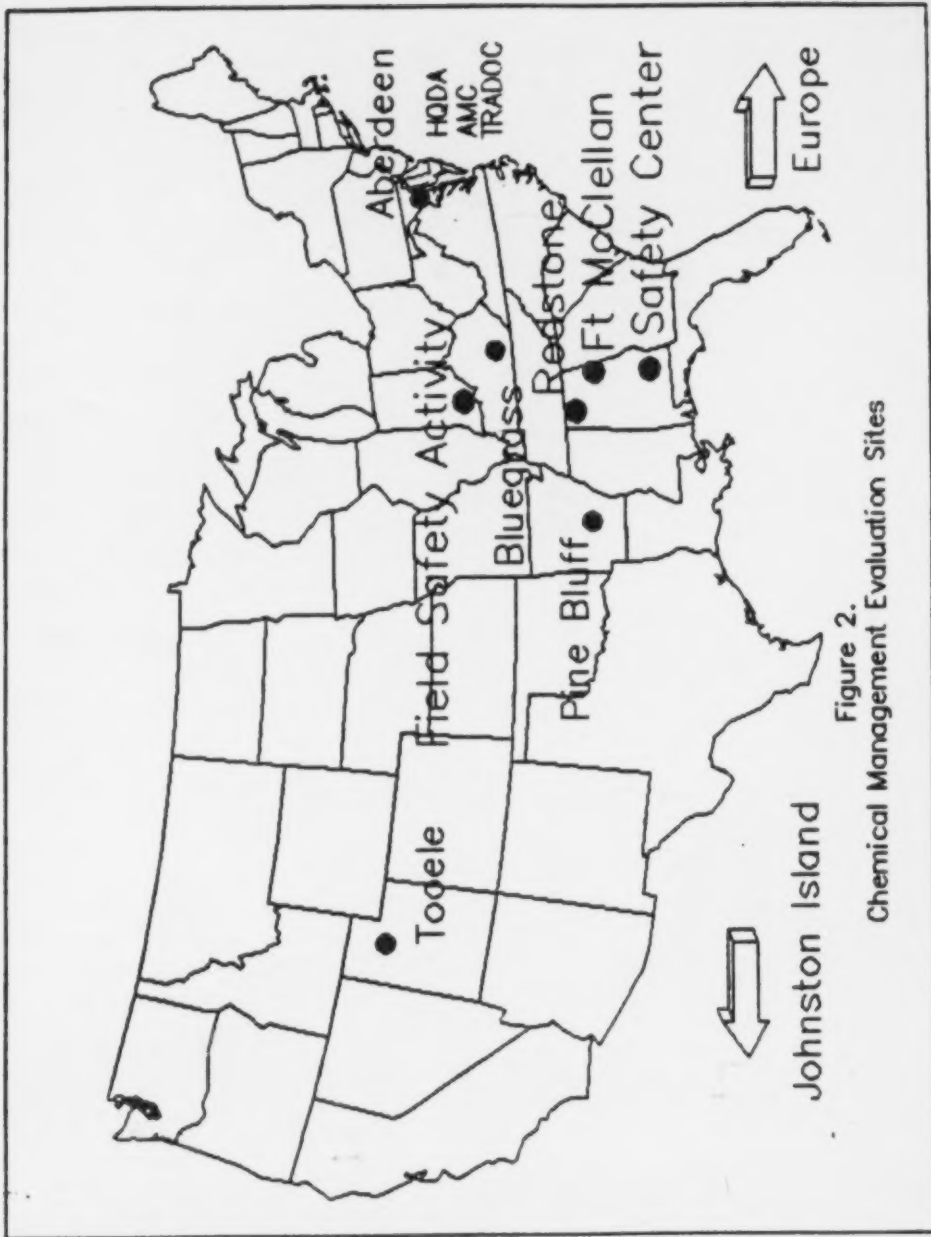
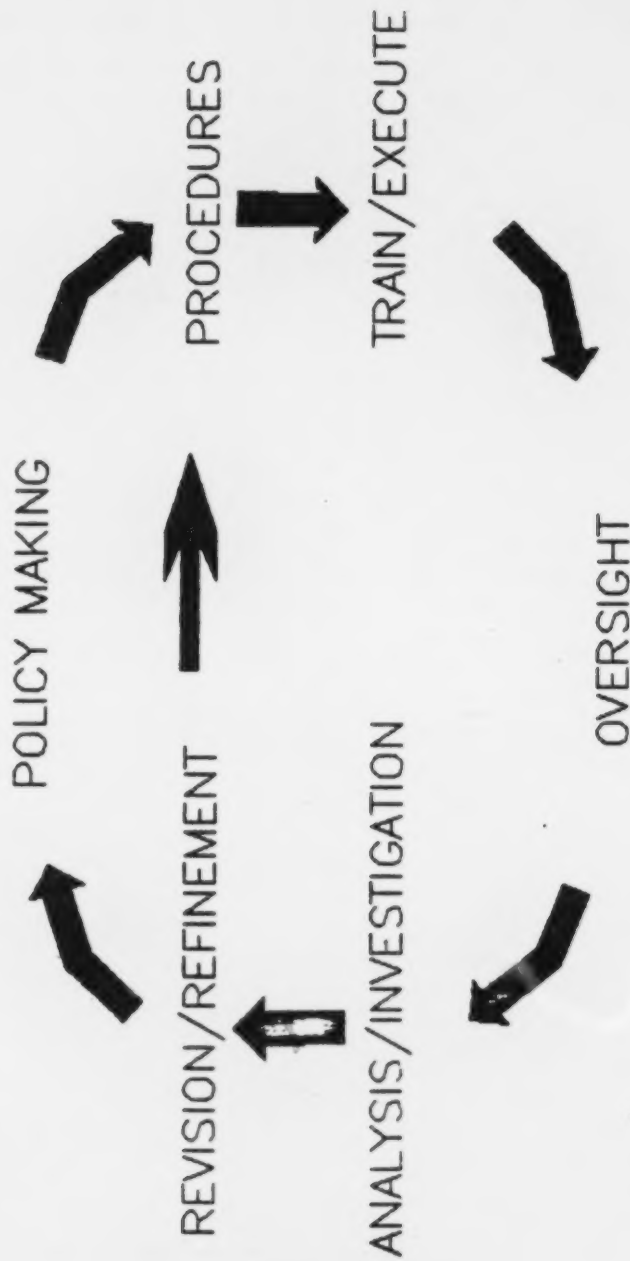


Figure 2.
Chemical Management Evaluation Sites

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SAFETY FUNCTIONS MODEL



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Figure 3.

SAFETY INSPECTION OF YALE UNIVERSITY, OBTAINED BY SUBCOMMITTEE
SUBSEQUENT TO HEARING

ARMY INFORMATION PAPER

DASG-RDZ
22 September 1988

SUBJECT: Army Safety Inspection of Biological Defense Contract Operations at Yale University

FACTS.

1. Prior to implementation of the Department of the Army (DA) requirement that all aspects of the biological defense program comply with Center for Disease Control-National Institutes of Health (CDC-NIH) guidelines, "Biosafety in Microbiological and Biomedical Laboratories", Army Biological Defense Program contract laboratories were not the subject of formal safety inspections. Such safety inspections were performed as an aspect of the Contracting Officer's Representatives site inspections. Formal safety inspection reports were not submitted since primary safety responsibility was vested with the university.
2. U. S. Army Medical Research and Development Command (USAMRDC) Policy 88-05, dated 24 May 1988, requires that biosafety level 3 (BL-3) contracts be inspected prior to contract award and annually thereafter.
3. The Yale University Arbovirus Research Unit (YARU) is a BL-3 laboratory. The YARU labs serve as a World Health Organization (WHO) Reference Center for Arboviruses. In addition to USAMRDC contracts, the YARU is supported by multiple national and international organizations including the CDC, NIH, WHO.
4. In accordance with DA requirements and USAMRDC Policy 88-05, the YARU was inspected on July 14, 1988 for compliance with CDC-NIH guidelines. Yale administrators reported to USAMRDC that other organizations providing support to the YARU have not conducted formal safety inspections separate from site visits to assess YARU scientific and technical capabilities.
5. Although the YARU was found to be in compliance with CDC-NIH guidelines for BL-3 operations, several recommendations were made which would enhance safety according to the laboratory experience of the U. S. Army Medical Research Institute of Infectious Diseases (USAMRIID). The safety report, comments by the USAMRIID Commander and Safety Officer are attached.
6. A follow-up inspection to assure compliance with recommended enhancements is scheduled prior to December 1988.

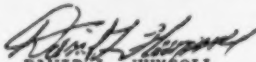
SGRD-UIZ-A (SGRD-UIZ-S)/18 Jul 88 (70-12)
SUBJECT: Trip Report

THRU Dep Cdr for Research FROM Cdr, USAMRIID DATE 26 Jul 88 CMT
Dep Cdr for Product Development cb/28
Dep Cdr for Admin

TO Safety Officer

1. The recommendations for improvements in biosafety are appropriate based on USAMRIID laboratory experience in BL-3 containment. Please clarify the point of whether the YARU laboratory meets the minimum criteria for BL-3 outlined in the CDC-NIH Guide to Biosafety in Microbiological and Biomedical Laboratories.

2. Given the identified inadequacies, particularly 4.a., b. and c., have there been any laboratory-acquired infections, either overt or as assessed by seroconversion, associated with these procedures or equipment?


DAVID L. HUXSOLL
Colonel, VC
Commanding

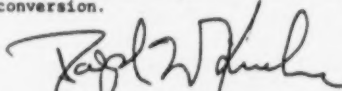
SGRD-UIZ-S

THRU Dep Cdr for Admin FROM Safety Officer DATE 26 Jul 88 CMT
Dep Cdr for Development USAMRIID bjm/733
Dep Cdr for Research

TO Commander, USAMRIID

1. No major violations of physical containment or practices as promulgated by the NIH-CDC biosafety guidelines were observed.

2. None of the inadequacies cited or any other practices currently employed at this laboratory have resulted in any infections with the agents studied under the BDRP program, as determined either clinically or by seroconversion.


RALPH W. KUEHNE
Safety Officer, USAMRIID

DISPOSITION FORM

For use of this form, see AR 385-15. The bracketed symbol is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

SGRD-UIZ-S(70-1z)

Trip Report

THRU	Dep Cmdr for Admin	Safety Officer	18 July 1988	CMT 1
	Dep Cmdr for Development	USAMRIID	Mr. Kuehne/bjm/733	
	Dep Cmdr for Research			

TO Commander, USAMRIID

1. Activity visited: Yale Arbovirus Research Unit (YARU), Yale University, New Haven, CT. Date of visit: 14 July 1988. Travel order #MRI 7-19.

2. Purpose of trip: To visit and inspect the BL-3 facilities of YARU to fulfill the requirement to review annually the safety policies and procedures of all USAMRIID contractors who perform contract work at the BL-3 containment level.

3. Persons contacted: Dr. Robert Shope, Director and Principal Investigator YARU, Dr. Greg Tichner, Principal Investigator, YARU, and Ms. Penny Hausser, Biosafety Officer, Yale University.

4. Fifty items concerning general lab safety were addressed. Another twenty one questions were asked dealing specifically with aspects of BL-3 containment. In addition, a visual inspection was made of the BL-3 laboratories and animal holding areas.

While the overall impression of the physical facility and the procedures policies and equipment being used was generally favorable and considered adequate to minimize the risk of infection to laboratory workers and animal caretakers, there were several notable exceptions. Inadequacies were defined and suggestions proposed. Findings and recommendations are itemized below, asterisks denoting problems considered to be significantly important to require initiation of corrective action as soon as possible.

*a. A Sorvall RC-2 centrifuge with Sorvall plastic 250 ml bottles is being used to centrifuge (2000x) viral agents classified at the BL-3 hazard level in a lower level laboratory adjacent to the BL-3 containment room. The sealed rotor is carried, after centrifugation is completed, to a class II biological safety cabinet and opened therein. According to researchers at USAMRIID, these bottles, as well as the rotor lid seal invariably leak. According to Dr. M. A. Vahey, who performed tests with a blue dye, the bottles, seals, and rotor used leak 100% of the time, creating a potential hazardous aerosol inside the chamber. Indeed, several seroconversions at USAMRIID have been attributed to this situation. The recommended solution is to evacuate the chamber before opening by means of a vacuum pump and tygon hose inserted into one of the available capped ports located on the side of the centrifuge. A disinfectant trap or in-line HEPA filter should be used to protect the pump from contamination. Instructions for modification and details of recommended operational procedures will be forwarded to Dr. Shope.

*b. Loose-fitting paper surgical masks are worn in rooms housing animal infected with BL-3 viruses. It is recommended that a tight-fitting HEPA-filtered half-face respirator be worn in rodent rooms and either a half-face respirator plus face shield or a full-face respirator be worn in rooms housing subhuman primates. Accordingly, a respirator program should be in effect in coordination with the Occupational Health Officer.

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*c. Air pressure gradients in BL-3 animal holding rooms are kept at 0.01" H₂O negative in relation to the "clean" corridor. It is recommended that at least 0.05" H₂O be maintained to prevent a positive condition when doors are opened. Actually, a gradient should be established from 0.05" to 1.0"-2.0" H₂O, related to the degree of contamination of various rooms in the area.

*d. No systems are on emergency power, not even critical ones such as ventilation. No emergency lighting is provided. It is recommended that emergency power be provided to maintain ventilation systems servicing the BL-3 areas, especially animal areas, and portable plug-in emergency lights be provided.

*e. Liquid waste material entering sinks, autoclave drains, and the floor drain in the "dirty" side autoclave room in the BL-3 animal holding area goes to a holding tank before release into the city sewage system. However, there is no heat treatment or disinfectant treatment; the dilution factor alone is relied upon to render the waste noninfectious. It is recommended that the biosafety manual which addresses BL-3 containment practices contain the instruction that several hundred ml of formalin, Lysol, Envirochem, or other appropriate disinfectant (not hypochlorite) be poured into sinks or drains whenever infectious material is accidentally or purposefully introduced into the system.

*f. Solid-front, short-sleeve shirts are worn in the infected animal area. Recommend that long-sleeve, ribbed-cuff, button-down-front shirts be provided.

g. No emergency alarm or any means of communication out of the BL-3 area is provided. It is recommended that such an alarm, phone, radio or other means is provided to request emergency medical assistance.

h. HEPA filters in the animal area exhaust plenums are not DOP tested when installed. Recommend a contract be negotiated to perform this testing when filters are changed.

i. Safety training and safety operating procedures for both chemicals and biological agents are currently being revised or developed. It is recommended that the forthcoming safety manual be reviewed annually, which was not done in the past.

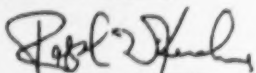
j. Magnehelic gauges are not installed in places where they can be read from outside the animal containment area, nor are they placed where the differential from each room can be ascertained. In addition, at least one of

SGRD-UII-S

SUBJECT: Trip Report

the present gauges is inaccurate, as it indicated a negative condition in an area where a smoke test showed positive. It is recommended that several manual Magnehelic (Dwyer Co., \$80) be installed on room doors and several other selected locations.

k. There are no pressure differential alarms.



RALPH W. KUEHNE
Safety Officer, USAMRIID